

EXHIBIT DX1

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

EXHIBIT A: CV

Timothy A. Ulatowski

1103 Arboroak Place · Herndon, Virginia 20170

703-404-2997

timothy.ulatowski@verizon.net

Regulatory Consultant/Medical Devices

Extensive Regulatory Experience ~ Risk Management ~ Technical Expert

A unique medical device consultant with extensive experience in both premarket evaluation of new medical devices and enforcement of FDA laws and regulations. Over 36 years of significant public health achievements, creating major regulatory programs and policies, developing and implementing strategic and risk management plans, and building collaborations with global regulatory partners and industry. Proven skills in advising industry on regulatory issues, assessing compliance and enforcement actions, evaluating premarket documents, managing and supervising large organizations, resolving complex technical and scientific problems of individual firms to those of national and international scope, and communicating to diverse audiences.

Selection of Notable Accomplishments

Hands on technical leadership of numerous compliance, enforcement and recall actions, many of national and global importance

Initiated use of novel corporate enforcement actions

Created effective internal quality management system used as a model program in FDA

Lead author of international guidance documents on aspects of the Global Harmonization Task Force medical device regulatory model adopted by many countries

Recognized in "Top 100" of medical device professionals/MDDI

Primary FDA reviewer of hundreds of Premarket Notifications, Investigational Device Exemptions, Premarket Approval Applications, recalls and compliance actions

Leader of team that developed the current FDA device standards program

Author of many key FDA premarket guidance documents, technical standards and publications

FDA key witness in federal court (US v Abtox), contributor to many FDA court cases, advisor to DOJ and FDA criminal investigations office

Lead for agency on many GAO, OMB and Congressional activities

FDA spokesperson to major press and to large audiences

HHS Team Leader and technical expert remediating Anthrax contamination of Senate and Postal Service buildings

Creator of FDA/CDC/EPA tripartite collaborations on chemical germicides and co-author of current FDA/EPA national regulatory scheme for chemical germicides

Co-author and collaborator on sharps injury prevention guidance, related OSHA and NIOSH regulations and policies, resulting in documented reduction of injuries

Recipient of numerous major FDA awards

Since FDA, Expert witness in numerous litigations

Since FDA, Expert trainer on behalf of FDA and US Dept of Commerce for foreign regulatory staff and FDA staff

Since FDA, successful completion of numerous premarket, postmarket and compliance activities for large and small manufacturers or entrepreneurs

Professional Experience

Regulatory Consultant, Medical Devices

April 2014 - Present

- Regulatory support in medical device areas of premarket, postmarket, compliance, combination products
- Expert witness in litigation

NSF Health Sciences (formerly Becker & Associates Consulting Inc.): Vice President, Regulatory and Compliance

September 2011 – March 2014

- Ensured effective and timely solutions to a variety of FDA regulatory and legal issues
- Provided expert advice and recommendations on premarket, quality systems, compliance and device reporting
- Trained industry executives and staff on FDA requirements

NDA Partners LLC: Principal

January 2011 – June 2012

- Advise clients on FDA regulations and law regarding product submissions, compliance and enforcement actions, and postmarket surveillance activities
- Serve as an expert witness in litigation
- Conduct due diligence

FDA, CDRH: Director, Office of Compliance and Senior Advisor for Enforcement

January 2003 – January 2011

- Managed and supervised office of four divisions and 180 professional staff responsible for ensuring compliance with medical device laws and regulations
- Directed FDA device quality system and bioresearch enforcement programs
- Directed inspection assignments and assessed quality system and bioresearch monitoring inspection reports and company/investigator/sponsor/IRB responses to determine violations
- Worked with all FDA districts, ORA and drug, biologics and food compliance executives to formulate enforcement strategies and actions
- Hands on evaluation and management of recalls, device advertising and promotion, MDRs, registration and listing, and medical device field resource allocation and prioritization
- Created new device enforcement policies and programs, directed implementation of the Commissioner's strategic action items, and participated in executive strategic planning at the agency and center levels
- Co-leader of FDA Medical Device Field Committee, an ORA/CDRH collaboration

- Initiated comprehensive training program for compliance staff and web-based information for the public
- Co-leader of 2010 user fee legislation post market committee, devising proposals and strategies with key Center and Agency staff for next round of legislation
- Senior Device Enforcement Advisor September 2010 – January 2011

FDA, CDRH: Head of USA Delegation, Global Harmonization Task Force and FDA representative to GHTF Study Group 1 Premarket

January 1995 - October 2010

- Managed the activities of the USA FDA participants to the GHTF Steering Committee and the five study groups; collaborated with USA industry task force members, USA leader on the GHTF Steering Committee for last four years
- Coordinated creation and review of documents and recommended agency decisions on pending documents to Center Director
- Primary author of several GHTF documents, including the original premarket “STED” document, and Global Model document, which are now used internationally
- Frequently trained international government staff on GHTF and FDA procedures

FDA, CDRH/Office of Device Evaluation: Director, Division of Dental, Anesthesiology, General Hospital, and Infection Control Devices

December 1996 – January 2003

- Managed premarket activities, such as review of premarket submissions and investigational applications, panel meetings, guidance development, and collaborative support for other CDRH offices
- Led development of the division during a major reorganization
- FDA lead on numerous international standards committees, reengineering task groups, and interagency task forces dealing with significant public health issues
- Succeeded in reducing review times while improving the quality and rigor of reviews
- Primary reviewer on numerous 510(k)s, IDEs, and PMAs
- Agency and ISO technical expert on medical device sterilization and disinfection

Prior FDA experience, short summary

Device Evaluation Associate Director, Branch Chief and front line 510(k), IDE, and PMA reviewer

Director, Investigational Device Staff, IDE application review and protocol advice

New Drug Evaluation Product Manager, NDA and IND activities and advisory committee exec sec

Microbiologist, National Center for Antibiotic Analysis, drug assessments

Prior to college and FDA career: US Army 1968 – 1971

Education

- Master of Science/Physiology with Biomedical Engineering emphasis, 1988 GPA 4.0

Georgetown University School of Medicine

- Bachelor of Science/Microbiology, 1974 cum laude

Pennsylvania State University

EXHIBIT DX2

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

EXHIBIT B: RELIANCE LIST

www.fda.gov

21 Code of Federal Regulations

Federal Food, Drug and Cosmetic Act

ASQ web site

Six Sigma web site

Quality Assurance Journal

AAOS web site

Additional reference material supplied by counsel attached hereto

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

Note: In connection with my work on individual cases before the MDL was created, I received Bates labeled documents. These are identified in this chart, with their original Bates numbers intact. Throughout my report, I included references to many of these documents. Counsel assisted me by providing the MDL Bates numbers for the documents I referenced.

| REVIEW MATERIALS SENT | DOC DATE (if appl) | BATES NOS. (if appl) |
|--|-----------------------------------|---------------------------------|
| 01 - PLEADINGS / PROTECTIVE ORDER | | |
| Pretrial Order #7: Protective Order | 4/29/2016 | |
| Ex. A to Proposed Pretrial Order #8 - Master Long Form Complaint | 8/24/2016 | |
| Defendants' Master Answer to Plaintiffs' Master Long Form Complaint and Jury Demand | 8/31/2016 | |
| Pretrial Order No. 17 - Amended Scheduling Order | 1/5/2017 | |
| Plaintiffs' Memorandum of Law in Support of Motion for Leave to Amend Master Long Form and Short Form Complaints to Add Claim for Punitive Damages | 4/21/2017 | |
| Exhibits re Plaintiff's Motion to add Punitive Damages; Exhibits 1-79 and Exhibits A-E | 4/21/2017 | |
| Walton Petition | 03/05/13 | |
| Walton Protective Order | 12/16/13 | |
| Affidavit of Robert Prestera | 04/22/13 | |
| 02 - PLAINTIFF'S EXPERT DISCLOSURES | | |
| Plaintiff's Preliminary Designation of Expert Witnesses | 11/11/14 | |
| Plaintiff's Supplemental Designation of Expert Witnesses and Reports | 04/17/15 | |
| 03 - PLAINTIFF-PRODUCED DOCUMENTS | | |
| N/A | | |
| 04 - 3M/ARIZANT'S DISCOVERY RESPONSES / EXPERT DISCLOSURES | | |
| Defendants' Preliminary Designation of Expert Witnesses | 12/16/14 | |
| | | |
| 05 - EXPERT REPORTS & DECLARATIONS | | |
| Expert Report of Dan Koenigshofer | 3/31/2017 | |
| Expert Report of Dr. Jonathan M. Samet | 3/30/2017 | |
| Expert Report of Dr. Michael J. Stonnington | | |
| Expert Report of Michael W. Buck | | |
| Expert Report of Said Elghobashi | 3/29/2017 | |
| Expert Report of William Jarvis | | |
| Expert Report of Yadin David (served in MDL) | | |

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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| Expert Report of Yadin David (served in Walton) | 09/28/15 | |
| Expert Report of Yadin David (served in Johnson) | 10/15/15 | |
| Report of Michael D. Freeman, MedDr, PhD, MPH | 04/11/15 | |
| Report of Paul J. Edelson, MD | 04/29/15 | |
| Report of Kenneth R. Diller, Sc.D., P.E. | 04/16/14 | |
| 06 - DEPOSITIONS [WITH EXHIBITS] | | |
| Augustine, Scott | 3/31/2017 | |
| Crowder, Robert | 3/16/2017 | |
| Danielson, Suzanne | 3/17/2017 | |
| Hansen, Gary | 11/2/2016 | |
| Hulse-Stevens, Michelle | 12/19/2016 | |
| Maharaj, Gary | 1/18/2017 | |
| Rock, John | 11/4/2016 | |
| Tan, Winston | 3/10/2017 | |
| Van Duren, Albert, Volume I | 11/7/2016 | |
| Van Duren, Albert, Volume II | 3/7/2017 | |
| Westlin, David | 12/16/2016 | |
| Woodwick-Sides, Teri | 12/8/2016 | |
| Zgoda, Karl | 2/24/2017 | |
| Ziaimehr, Allen | 3/3/2017 | |
| Bergstrom, Troy | 02/18/15 | |
| Clyburn, Terry (MD) | 12/22/14 | |
| Dholakia, Nizar (MD) | 10/10/14 | |
| Hansen, Gary | 02/11/15 | |
| Lewallen, David (MD) | 09/25/14 | |
| Maharaj, Gary | 02/19/15 | |
| Rock, John | 02/19/15 | |
| Sessler, Daniel | 05/28/15 | |
| Sides, Teri | 03/03/15 | |
| Van Duren, Albert | 02/13/15 | |
| Walton, Tommy | 09/11/14 | |
| Walton, Wilma | 09/11/14 | |
| Westlin, David | 02/17/15 | |
| Wilson, Pamela (MD) | 04/21/15 | |
| Zgoda, Karl | 02/12/15 | |
| Johnson, Timothy | 3/6/2015 | |
| Westlin, David | 7/14/2015 | |
| Bergstrom, Troy | 7/15/2015 | |
| Rock, John | 7/16/2015 | |
| Zgoda, Karl | 7/22/2015 | |
| Rockford, Melissa (MD) | 8/6/2015 | |
| Clough, Lisa (MD) | 8/11/2015 | |
| Hansen, Gary | 8/27/2015 | |

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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|---|------------|---|
| Maharaj, Gary | 8/19/2015 | |
| Woodwick-Sides, Teryl | 9/15/2015 | |
| Van Duren, Al | 9/10/2015 | |
| Hawkinson, Dana (MD) | 11/11/2015 | |
| Hendricks, Kelly (MD) | 8/18/2015 | |
| Key, Vincent (MD) | 9/17/2015 | |
| Tan, Winston | 8/26/2015 | |
| 07 - MEDICAL RECORDS | | |
| N/A | | |
| 08 - 3M/ARIZANT DOCUMENTS PRODUCED | | |
| Bair Hugger Model 750 Labeling Documents | | |
| Device Design and Re-Design File | | 3M00005343 - 3M00005975, 3M00048780 - 3M00048782 |
| 510(k) Documents | | 3M00005976 - 3M00006290 |
| Additional 510(k) documents | | 3M00057816 - 3M00058560 |
| Instructions for Use - Bair Hugger Blankets | | 3M00052020 - 3M00052025 |
| Additional Regulatory materials | | 3MBH00500455- 3MBH00500464 |
| | | 3MBH00127752- 3MBH00129010 |
| | | 3MBH00501665- 3MBH00501957 |
| | | 3MBH00500654- 3MBH00500655 |
| | | 3MBH00500671- 3MBH00500674 |
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| | | 3MBH00501117 |
| | | 3MBH00501121- 3MBH00501124 |
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| | | 3MBH00501348 |
| | | 3MBH00501414 |
| | | 3MBH00501446 |
| | | 3MBH00501471 |
| | | 3MBH00502015 |
| Additional Documents Produced | | 3MBH01517606- 3MBH01518524 |

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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| | | 3M00051756-52116 |
| | | 3M00052120-74119 |
| | | 3M00074121-74181 |
| | | 3M00074183-74375 |
| 09 - RELEVANT LITERATURE | | |
| N/A | | |
| Charnley J., Eftekhari N. Postoperative infection in total prosthetic replacement arthroplasty of the hip joint. The British Journal of Surgery. 1969. | 1969 | |
| Franco J., et al. Airborne contamination in orthopedic surgery. Clinical Orthopedics and Related Research. 1976. | 1976 | |
| Adair F. Nosocomial Serratia outbreak: Guilt by association or scientific investigation? Lancet. 1981. | 1981 | |
| Lidwell O.M., et al. Effect of ultraclean air in operating rooms on deep sepsis in the joint after total hip or knee replacement: a randomized study. British Medical Journal. 1982. | 1982 | |
| Lidwell O.M., et al. Bacteria isolated from deep joint sepsis after operation for total hip or knee replacement and the sources of the infections with Staphylococcus aureus. Journal of Hospital Infection. 1983. | 1983 | |

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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|---|------|--|
| Sautter R.L., et al. Serratia marcescens meningitis associated with a contaminated benzalkonium chloride solution. Infection Control. 1984. | 1984 | |
| Lidwell O.M., et al. Ultraclean air and antibiotics for the prevention of postoperative infection. Acta Orthopaedica Scandinavica. 1987. | 1987 | |
| Sessler D., et al. Hypothermia during epidural anesthesia results mostly from redistribution of heat within the body, not heat loss to the environment. Anesthesiology. 1989. | 1989 | |
| Lewis A.M., et al. A hospital outbreak of Serratia marcescens in neurosurgical patients. Epidem. Inf. 1989. | 1989 | |
| Lennon R.L., et al. Evaluation of a forced-air system for warming hypothermic postoperative patients. Anesthesia & Analgesia. 1990. | 1990 | |
| Sessler D.I., & Ponte J. Shivering during epidural anesthesia. Anesthesiology. 1990. | 1990 | |
| Moayeri A., et al. Pre-induction skin-surface warming prevents redistribution hypothermia. Anesthesiology. 1991 | 1991 | |
| Sessler D., et al. Perioperative thermal insulation. Anesthesiology. 1991. | 1991 | |
| Camus Y., et al. Thermal balance using a forced-air warmer (Bair Hugger) during abdominal surgery. Anesthesiology. 1991. | 1991 | |
| Feroe DD & Augustine SD. Hypothermia in the PACU. Critical Care Nursing Clinics of North America 1991. | 1991 | |
| Hall A.C. & Teenier T. Bair Hugger warmer does not increase microbial contamination in the operating room. 1991. | 1991 | |
| Hynson J.M. & Sessler D. Intraoperative warming therapies: A comparison of three devices. Journal of Clinical Anesthesia. 1992. | 1992 | |
| Sessler D. Perioperative Temperature Control. The Western Journal of Medicine. 1992. | 1992 | |
| Camus Y. et al. Leg warming minimizes core hypothermia during abdominal surgery. Anesthesia & Analgesia. 1993. | 1993 | |
| Glosten B., et al. Preanesthetic skin-surface warming reduces redistribution hypothermia caused by epidural block. Anesthesia & Analgesia. 1993. | 1993 | |

CHART OF MATERIALS SENT TO TIMOTHY ULATOWSKI

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| Hynson J.M., et al. The effects of preinduction warming on temperature and blood pressure during propofol/nitrous oxide anesthesia. <i>Anesthesiology</i> . 1993. | 1993 | |
| Just B., et al. Prevention of intraoperative hypothermia by preoperative skin surface warming. <i>Anesthesiology</i> . 1993. | 1993 | |
| Sessler D. Perianesthetic thermoregulation and heat balance in humans. <i>The FASEB Journal</i> . 1993. | 1993 | |
| Zink R., et al. Convective warming therapy does not increase the risk of wound contamination in the operating room. <i>Anesthesia & Analgesia</i> . 1993. | 1993 | |
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EXHIBIT DX3

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

Exhibit C: Prior Depositions and Testimony

Prior Depositions and Court Testimony

Depositions:

University of Pittsburgh of the Commonwealth System of Higher Education d/b/a University of Pittsburgh v. Varian Medical Systems, Inc.

Civil Action No.: 2:08-cv-01307 (USDC, Western District of Pennsylvania)

David M. Kloss, et al, v. I-Flow Corporation, et al, Case No. 2:10-cv-00295-JFC (USDC, Western District of Pennsylvania)

Retractable Technologies, Inc. and Thomas Shaw v. Becton, Dickinson and Company, Civil Action No.2:08-cv-16 (Folsom) (USDC, Eastern District of Texas Marshall Division)

Diagnostic Devices Inc, v. Pharma Supply, Inc. et al, Diagnostic Devices Inc, v. Taidoc Technology Corporation, Case No.3:08-CV-00149-MOC-DCK (USDC, Western District of North Carolina, Charlotte Division)

Brenda F. Kitrosser v. Nuvasive, Inc. et al., Case No: 37-2009-00099700-CU-MM-CTL [Consolidated with Case No: 37-2010-00099400-CU-PO-CTL] (Superior Court of the State of California In and For the County of San Diego, Central Branch)

Superior Court of New Jersey, Law Division, Atlantic County
In re Pelvic Mesh/ Gynecare Litigation, Case No.291 CT, Master Case 6341-10

Jackson, et al v DePuy Orthopedics, No. CAL 10-32147 (Prince George's County, MD)

Strum v. DePuy Orthopaedics, Inc., et al., No. 11 L 009352 (Circuit Court, Cook County, Illinois)

Dorney-Madgitz v. DePuy Orthopedics, Inc., et al., 5:11-cv-001240-RBS (USDC, Eastern District of Pennsylvania)

Weinstat, et al. v. Dentsply International, et al., San Francisco Superior Court No. CGC-04-432370

Braun v. Medtronic Sofamor Danek, USDC, District of Utah, Central Division, Case 2:10-cv-01283

Connie Schubert and Kevin Schubert v. Ethicon, Inc., Ethicon Women's Health and Urology, a division of Ethicon, Inc., Gynecare, and Johnson and Johnson, et. al., In the Circuit Court of Jasper County, Missouri at Joplin, Case No. 10AO-CC00219

Sekisui America Corporation and Sekisui Medical Co., Ltd. v. Richard Hart and Mary Louise Trudel-Hart, USDC, Southern District of New York, Case 1:12-cv-03479-SAS (for Plaintiff) Carol Lewis and Kenneth Lewis v. Ethicon, USDC, Southern District of West Virginia, MDL No. 2327

April Christine Cabana v. Medtronic Inc. (et al), Superior Court of the State of California, County of Los Angeles, Case No. BC 465 313

Christine Napolitano v. Synthes, Inc., USDC, District of Connecticut, Civil Action 3:09-CV-00828

Herlihy-Paoli v. DePuy Orthopedics, Inc., et al, 3:12-CV-04975-K (USDC, Northern District of Texas, Dallas Division)

City of Lakeland Employees Pension Plan v. Baxter International Inc., No. 10-cv-6016, USDC, Northern District of Illinois

Smith v. Baxano, Inc. et al, Superior Court of Washington for Snohomish County, Case No. 13-2-02714-1

Andrea Smith v DePuy Orthopedics, et al., District Court of Tulsa County, Oklahoma, No. CJ-2011-05804

Zimmer NexGen Knee Implant Products Liability Litigation, USDC, Northern District of Illinois, Eastern Division, MDL No. 2272, Master Docket No.:1:11-cv-05468

Sandra Garcia v Rodolfo J. Walss, MD, Johnson & Johnson, Inc. and Ethicon, Inc., District Court, 103rd Judicial District, Cameron County, Texas, Cause No. 2013-DCL-3511-D

Laura Ness v Depuy Orthopedics, Inc., et al., In the Circuit Court for Baltimore City, Case No. : 24-C-14-002465

Consolidated Fresenius Cases, Commonwealth of Massachusetts, Middlesex SS., Superior Court Department of the Trial Court, Civil Action No. 2013-03400-O Session

Aoki, Christopher, Greer, Klusmann, Peterson, Thibodeau (separate Plaintiffs) v DePuy Orthopedics, Inc. et al., USDC, Northern District of Texas, Dallas Division, MDL No. 2244

Center City Periodontists, P.C., et al. v. Dentsply International, Inc., Eastern District of Pennsylvania, Civil Action No. 10-00744.

Michael Parker, Individually and Amy Parker, Individually v. Veronica A. Vasicke, MD; Bluegrass Orthopedics & Hand Care, PSC; and I-Flow Corporation, Fayette Circuit Court, Eighth Division, Civil Action No. 12-CI-3543.

Mary N. Insall, as the Executrix of the estate of John N. Insall, Petitioner and Zimmer, Inc. Respondent, American Arbitration Association, Chicago, Illinois, Case No. 01-15-0002-0601.

Dennis Brian Anders, et al. v Medtronic, Inc and Medtronic Sofamor Danek USA Inc, State of Missouri, 22nd Judicial Circuit Court, City of St. Louis, Case File No. 1322-CC10219.

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Scott Shields and Phyllis Shields v. Medtronic, Inc., Matthew McCormick, Southwestern Illinois Health Facilities, Inc. a/k/a Anderson Hospital and Dr. El S. Lin, Circuit Court, Third Judicial Circuit, Madison County, Illinois, Case No. 2014-L-1222.

Court Testimony:

Strum v. DePuy Orthopaedics, Inc., et al., No. 11 L 009352 (Circuit Court, Cook County, Illinois)

Brenda F. Kitrosser v. Nuvasive, Inc. et al., Case No: 37-2009-00099700-CU-MM-CTL [Consolidated with Case No: 37-2010-00099400-CU-PO-CTL] (Superior Court of the State of California In and For the County of San Diego, Central Branch)

Weinstat, et al. v. Dentsply International, et al., San Francisco Superior Court No. CGC-04-432370

Sekisui America Corporation and Sekisui Medical Co., Ltd. v. Richard Hart and Mary Louise Trudel-Hart, USDC, Southern District of New York, Case 1:12-cv-03479-SAS

Becky S. Anderson v. Medtronic, Inc. (et al), Superior Court for the State of Washington, County of King, No. 12-2-17928-0 SEA

Donald Gustafson v. Zimmer, Inc., District Court, Collin County, Texas, 366th Judicial District, Cause No. 366-03111-2011

Herlihy-Paoli v. DePuy Orthopedics, Inc., et al, 3:12-CV-04975-K (USDC, Northern District of Texas, Dallas Division)

Andrea Smith v DePuy Orthopedics, et al., District Court of Tulsa County, Oklahoma, No. CJ-2011-05804

Alysia Ogburn-Sisneros, as personal representative of the estate of Billy Ogburn, Sr., Plaintiff v. Fresenius Medical Care Holdings, Inc.d/b/a Fresenius Medical Care North America, Inc, Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., Fresenius USA Marketing, Inc., and

Fresenius USA Sales, Inc., Defendants, Commonwealth of Massachusetts, Superior Court Department, Civil Action No. 13-5050

Center City Periodontists, P.C., et al. v. Dentsply International, Inc., Eastern District of Pennsylvania, Civil Action No. 10-00744.

Aoki, Christopher, Greer, Klusmann, Peterson, Thibodeau (separate Plaintiffs) v DePuy Orthopedics, Inc. et al., USDC, Northern District of Texas, Dallas Division, MDL No. 2244

Andrews, Davis, Metzler, Rodriguez, Standerfer, Weiser v. Depuy Orthopedics, USDC, Northern District of Texas, Dallas Division, MDL 3:11-MD-2244-K.

Mary N. Insall, as the Executrix of the estate of John N. Insall, Petitioner and Zimmer, Inc. Respondent, American Arbitration Association, Chicago, Illinois, Case No. 01-15-0002-0601.

EXHIBIT DX4

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

UNITED STATES DISTRICT COURT

DISTRICT OF MINNESOTA

In Re Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 15-2666
(JNE/FLN)

PLAINTIFFS,

v.

3M COMPANY and ARIZANT

HEALTHCARE, INC.

Supplemental Report of Timothy A. Ulatowski, MS, BS

Purpose of Supplement: This supplemental report provides my opinions regarding the August 30, 2017, Notice from the Food and Drug Administration entitled Information About the Use of Forced Air Thermal Regulating Systems-Letter to Health Care Providers.¹ It is new information made available after my report dated June 2, 2017. This supplemental report incorporates my June 2, 2017 report in its entirety.

Discussion: I have reviewed the Notice in its entirety and rely upon its content. From time to time FDA posts on its web site Letters to Health Care Providers about safety concerns regarding medical devices.² Currently FDA has 13 such notices posted. Letters to Health Care Providers is one type of FDA safety information.³ FDA notes on its Medical Device Safety web page that it “monitors reports of adverse events and other problems with medical devices and alerts health professionals and

¹ FDA Notice on Forced Air Warming Devices,
<https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/ucm573837.htm>.

² FDA Letters to Health Care Providers,
<https://www.fda.gov/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm>.

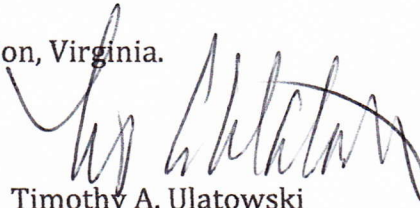
³ See FDA Safety Information,
<https://www.fda.gov/MedicalDevices/Safety/default.htm>.

the public when needed to ensure proper use of devices and the health and safety of patients.”

1. The August 30, 2017, FDA Notice to Health Care Providers is consistent with the opinions in my June 2, 2017 report.
2. The Notice does not cause me to change or modify any of the opinions in my June 2, 2017 report.
3. The August FDA Notice provides ample evidence that FDA conducted a thorough review of existing data and information on the subject of surgical site infections alleged to have been caused by forced air warming devices during surgery. The Notice states “FDA collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements.” These types of data are in evidence in this litigation and referenced in my June 2, 2017 report.
4. I will rely on the FDA Notice at trial.

I certify under penalty of perjury that the statements in my expert report dated June 2, 2017, and in this supplement are true and correct.

Executed on this date in Herndon, Virginia.



Timothy A. Ulatowski
September 8, 2017

EXHIBIT DX5

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

1

1 UNITED STATES DISTRICT COURT

2 DISTRICT OF MINNESOTA

3 - - - - -

4 In Re:

5 Bair Hugger Forced Air Warming

6 Products Liability Litigation

7

8 This Document Relates To:

9 All Actions MDL No. 15-2666 (JNE/FLM)

10 - - - - -

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13 DEPOSITION OF TIMOTHY A. ULATOWSKI

14 VOLUME I, PAGES 1 - 414

15 JULY 7, 2017

16

17

18 (The following is the deposition of TIMOTHY

19 A. ULATOWSKI, taken pursuant to Notice of Taking

20 Deposition, via videotape, at the Renaissance

21 Arlington Capital View Hotel, 2800 Potomac Avenue,

22 Arlington, Virginia, commencing at approximately 9:02

23 o'clock a.m., July 7, 2017.)

24

25

1 APPEARANCES:

2 On Behalf of the Plaintiffs:

3 Mark D. Bankston
4 KASTER, LYNCH, FARRAR & BALL LLP
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8 MESHBESHER & SPENCE, LTD.
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11 On Behalf of Defendants:

12 Christin Jaye Eaton and Jeffrey M.
13 Wojciechowski
14 FAEGRE BAKER DANIELS LLP
15 2200 Wells Fargo Center
16 90 South Seventh Street
17 Minneapolis, Minnesota 55415

18 ALSO APPEARING:

19 Ronald M. Huber, Videographer

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| 1 | I N D E X | | |
| 2 | EXHIBITS | DESCRIPTION | PAGE MARKED |
| 3 | Ex 1 | Medical Devices and the Public's | |
| 4 | | Health, The FDA 510(k) Clearance | |
| 5 | | Process at 35 years | 70 |
| 6 | 2 | Exhibit B to Ulatowski expert | |
| 7 | | report | 89 |
| 8 | 3 | Letter, July 10, 1990, Augustine | |
| 9 | | to FDA, 3MBH00047446 | 124 |
| 10 | 4 | K903360, Substantial Equivalence | |
| 11 | | (SK) Decision Making Documentation, | |
| 12 | | 3MBH00047439-42 | 164 |
| 13 | 5 | Letter stamped April 30, 1998, | |
| 14 | | Ulatowski to Augustine, | |
| 15 | | 3MBH01696526-7 | 216 |
| 16 | 6 | Letter dated August 16, 2010, | |
| 17 | | Westlin to Wood, 3MBH00970030-1 | 226 |
| 18 | 7 | Risk analysis spreadsheet, | |
| 19 | | 3MBH00553184 | 256 |
| 20 | 8 | Annotated document, 3MBH01617179- | |
| 21 | | 81 | 312 |
| 22 | 9 | Letter dated June 1, 2000, | |
| 23 | | Westlin to Office of Device | |
| 24 | | Evaluation, 3MBH00046971-2 | 335 |
| 25 | 10 | NSF Health Sciences invoice | |

4

1 dated June 21, 2017, three

2 pages 404

3 11 ECRI article, Forced-Air Warming

4 and Surgical Site Infections 405

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7 WITNESS EXAMINATION BY PAGE

8 Thomas A. Ulatowski Mr. Bankston 5

9 Ms. Eaton 404

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1 P R O C E E D I N G S

2 (Witness sworn.)

3 TIMOTHY A. ULATOWSKI

4 called as a witness, being first duly sworn,
5 was examined and testified as follows:

6 ADVERSE EXAMINATION

7 BY MR. BANKSTON:

09:02:05 8 Q. Can you state your name and what you do for
09:02:07 9 a living, sir.

09:02:07 10 A. Timothy Ulatowski. I'm a regulatory
09:02:10 11 consultant.

09:02:10 12 Q. Okay. I understand that you were asked to
09:02:15 13 address some of the allegations in plaintiffs' master
09:02:19 14 long form complaint as well as in the report of Dr.
09:02:22 15 Yadin David; is that correct?

09:02:22 16 A. That's correct.

09:02:23 17 Q. Okay. I also understand I don't need to
09:02:27 18 explain to you anything about a deposition today. I
09:02:29 19 would assume you're pretty familiar with this process.

09:02:30 20 A. Pretty familiar.

09:02:31 21 Q. Okay. The first thing I want to talk to you
09:02:35 22 about: When you were asked to do work on this case,
09:02:40 23 you generated a report; correct?

09:02:41 24 A. That's correct.

09:02:42 25 Q. Okay. Can you tell me how much time you

09:02:46 1 spent reviewing materials and preparing your opinions
09:02:49 2 in this case?

09:02:51 3 A. I don't have an exact time. I haven't added
09:02:55 4 up all my time for this particular report. I could do
09:03:00 5 so afterwards, but it would be a guess.

09:03:03 6 Q. Okay. Why don't you go ahead and take a
09:03:05 7 guess. I want just a general idea of how long this
09:03:08 8 took.

09:03:08 9 A. Well I think we have the vouchers, so I
09:03:10 10 think we have a more accurate accounting for the time,
09:03:12 11 rather than me guessing.

09:03:15 12 Q. Do you --

09:03:15 13 MS. EATON: For courtesy, Mark, he doesn't
09:03:15 14 want you to guess.

09:03:16 15 MR. BANKSTON: Okay. Well I'd like to know
09:03:17 16 for the purpose of this deposition.

09:03:18 17 MS. EATON: We've produced the invoices.

09:03:20 18 MR. BANKSTON: Okay. All right.

09:03:21 19 Q. So sitting here today, though, without the
09:03:24 20 benefit of your invoices, you don't know whether
09:03:26 21 you've spent 10 hours, a hundred hours, a thousand
09:03:28 22 hours.

09:03:29 23 MS. EATON: Object to the form of the
09:03:30 24 question.

09:03:30 25 A. Well let's not be absurd, but -- at the low

09:03:33 1 end, but my vouchers will attest to the hours I
09:03:36 2 reported to the attorneys and -- and the hours I was
09:03:40 3 paid for.

09:03:40 4 Q. Were the hours you spent in this case more,
09:03:43 5 less, or generally the same than you would have done
09:03:45 6 in comparable litigations?

09:03:48 7 MS. EATON: Object to the form of the
09:03:49 8 question.

09:03:49 9 A. Well com -- comparable in what way? In
09:03:52 10 regards to the numbers of documents or --

09:03:54 11 Q. The time.

09:03:55 12 A. -- an MDL or --

09:03:57 13 Q. The time you spent generating the report.

09:04:00 14 A. I would say it's probably in the range,
09:04:02 15 average range.

09:04:02 16 Q. Same things you've done in other prior
09:04:05 17 medical device cases in other words.

09:04:06 18 A. I believe so.

09:04:07 19 Q. Okay.

09:04:07 20 A. About that range.

09:04:08 21 Q. All right. Now sir, you spent about 30
09:04:19 22 years or more with the FDA; is that correct?

09:04:21 23 A. Almost 37.

09:04:22 24 Q. Okay. Now I understand you've obviously had
09:04:26 25 communications with these lawyers about the facts of

09:04:29 1 the case, the allegations, the expert reports, et
09:04:31 2 cetera, in coming to your opinions; correct?

09:04:34 3 MS. EATON: Object to the form of the
09:04:35 4 question.

09:04:36 5 A. Well I had discussions with the attorneys
09:04:37 6 about the case and about the experts --

09:04:43 7 MS. EATON: And -- and I would just caution
09:04:44 8 you that you're not entitled to ask about the
09:04:47 9 discussions that he's had with us.

09:04:49 10 MR. BANKSTON: Sure.

09:04:49 11 Q. I just want to know: You spoke to attorneys
09:04:52 12 before writing your report.

09:04:53 13 A. Sure.

09:04:53 14 Q. Okay. I'm wondering if you ever had
09:04:56 15 communications where you discussed your matters
09:04:58 16 relating to your time you were at the FDA.

09:05:00 17 MS. EATON: Object. You can't --

09:05:01 18 He's not allowed to answer what we talked
09:05:04 19 about.

09:05:04 20 Q. Sir, you have had personal involvement with
09:05:06 21 the Bair Hugger over your time with the FDA?

09:05:08 22 A. I had one episode of involvement.

09:05:10 23 Q. You've actually been the signatory on
09:05:13 24 several documents relating to the Bair Hugger.

09:05:14 25 A. I know that I've signed at least one in

09:05:18 1 regard to a warning letter.

09:05:19 2 Q. The approval for the device came through
09:05:21 3 your office of which you have direct control; correct?

09:05:24 4 A. No.

09:05:26 5 MS. EATON: Object to the form of the
09:05:26 6 question.

09:05:26 7 Q. The Bair Hugger -- which --

09:05:27 8 Which division of the FDA was responsible
09:05:29 9 for approving the Bair Hugger?

09:05:30 10 A. It was the Cardiovascular Division.

09:05:32 11 Q. Okay. So in terms of the 510(k), it's your
09:05:36 12 testimony you've had no involvement whatsoever with
09:05:37 13 the 510(k) approval of a Bair Hugger device.

09:05:39 14 A. I did not work in the Cardiovascular
09:05:41 15 Division. And it's not an approval, it's called a
09:05:44 16 clearance.

09:05:45 17 Q. Okay. So in terms of when the 510(k)
09:05:47 18 clearance is granted to any Bair Hugger device, your
09:05:49 19 name will not be on those documents.

09:05:51 20 A. That's correct.

09:05:52 21 Q. Okay. With regard to the involvement you
09:05:55 22 did have with the Bair Hugger in terms of things that
09:05:58 23 happened to you in connection with your government
09:06:00 24 experience before you were ever retained in this case,
09:06:02 25 have you had discussions with counsel about those?

09:06:06 1 A. In regard to the --

09:06:10 2 Well again, that's discussion with counsel,
09:06:11 3 so I don't know if I --

09:06:13 4 Q. Well sir, you -- you understand that events
09:06:14 5 that happened to you factually that relate to the
09:06:17 6 facts of this case make you a witness in this case;
09:06:21 7 correct?

09:06:21 8 MS. EATON: Object to the form of the
09:06:22 9 question.

09:06:22 10 A. I -- I guess I don't understand your
09:06:24 11 statement. Could you explain it to me?

09:06:26 12 Q. Sure. You understand that certain witnesses
09:06:27 13 like you are sometimes engaged and paid to provide
09:06:30 14 expert testimony in a lawsuit; correct?

09:06:32 15 A. Correct.

09:06:33 16 Q. And then there are other types of witnesses,
09:06:35 17 witnesses who, maybe from their own personal
09:06:37 18 experience, from their own facts and the bits that
09:06:42 19 they perceived with their two eyes, come and testify
09:06:44 20 in the case as well; correct?

09:06:46 21 A. Yes, I understand those are -- that's
09:06:47 22 another type of witness.

09:06:47 23 Q. Both of those things can apply to you;
09:06:50 24 correct?

09:06:50 25 MS. EATON: If you would like to ask him

09:06:52 1 what he knows, you can go ahead.

09:06:53 2 MR. BANKSTON: I --

09:06:54 3 Objection basis?

09:06:56 4 MS. EATON: Yeah.

09:06:56 5 MR. BANKSTON: Like is that a basis for an
09:06:58 6 objection?

09:06:58 7 MS. EATON: Yeah. Object to the form.

09:06:59 8 MR. BANKSTON: Okay. Thank you.

09:07:00 9 A. I had involvement in one brief episode with
09:07:05 10 the Bair Hugger, --

09:07:05 11 Q. Okay.

09:07:06 12 A. -- if that's your question.

09:07:06 13 Q. Sure. And what actually my question was
09:07:09 14 after we had covered that: Have you had discussions
09:07:11 15 about that episode with counsel?

09:07:14 16 A. Inasmuch as I reviewed documentation in the
09:07:17 17 MDL.

09:07:17 18 Q. Okay. Have you had written communications
09:07:19 19 with counsel about your time relating to -- in your
09:07:23 20 time at the FDA relating to the Bair Hugger?

09:07:25 21 A. I don't believe so.

09:07:26 22 Q. Okay. You spent your career with something
09:07:31 23 in the Office of Device Evaluation; is that right?

09:07:32 24 A. That was a great deal of my experience at
09:07:37 25 FDA, but not my only experience.

12

09:07:40 1 Q. Okay. And then you were also a director in
09:07:40 2 the Center for Devices and Radiological Health?

09:07:43 3 A. I was -- I was one of half a dozen
09:07:45 4 directors, office directors.

09:07:46 5 Q. Right. A director?

09:07:47 6 A. I was a director.

09:07:48 7 Q. Okay. After leaving the FDA, you started
09:07:52 8 testifying in numerous lawsuits relating to medical
09:07:56 9 devices.

09:07:57 10 A. "Numerous" meaning --

09:07:59 11 Q. More than one.

09:08:00 12 A. Yes.

09:08:00 13 Q. Okay. In fact, a significant source of your
09:08:04 14 income, to come to courtrooms and rooms like this and
09:08:09 15 give testimony that medical devices which are alleged
09:08:12 16 to be unsafe are in fact safe.

09:08:14 17 MS. EATON: Object to the form of the
09:08:15 18 question.

09:08:16 19 A. Well the -- the aspects of the case are --
09:08:19 20 are unique in every instance in regard to what are the
09:08:21 21 issues at hand, and I testify for -- for defendants
09:08:25 22 and plaintiffs.

09:08:26 23 Q. Well when you're on the plaintiff's side,
09:08:27 24 it's a medical device company though; right?

09:08:29 25 A. Not always, no.

09:08:30 1 Q. Okay. Do you --

09:08:32 2 Have you ever given testimony, expert

09:08:33 3 opinion on behalf of a patient who has been alleged to

09:08:36 4 be hurt by a medical device?

09:08:38 5 A. Yes.

09:08:38 6 Q. Okay. Can you tell me about that.

09:08:40 7 A. It was in -- you know, what do you call

09:08:45 8 them -- test cases or -- for -- in an MDL against a

09:08:51 9 company called Fresenius.

09:08:52 10 Q. Okay.

09:08:52 11 A. The product was -- was a hemodialysis fluid,

09:08:58 12 GranuFlo. And there's another that was just -- that

09:09:02 13 was involved as well.

09:09:02 14 Q. Okay. What year was that?

09:09:04 15 A. Well I think that was probably two to three

09:09:07 16 years ago.

09:09:07 17 Q. Okay. You've had dozens of cases since

09:09:14 18 you've left the FDA; correct?

09:09:17 19 A. Well I've been engaged in a number of cases.

09:09:20 20 Some have not gone very far for one reason or another.

09:09:24 21 The ones that have progressed to a deposition and to

09:09:28 22 trial I list, and I could provide lists of what I've

09:09:32 23 been engaged in. Others have not gone far because

09:09:36 24 case -- as you know, cases settle or the client

09:09:39 25 doesn't like what I have to say or whatever, whatever

09:09:42 1 the issue is.

09:09:43 2 Q. Okay. You're currently paid \$500 an hour to
09:09:47 3 give opinions in this case?

09:09:49 4 A. Yes.

09:09:49 5 Q. Okay. Now you don't consult or do anything
09:09:53 6 for the FDA currently; correct?

09:09:55 7 A. I haven't for a little bit of time, couple
09:09:59 8 years, so --

09:10:00 9 Before that, after my departure from FDA, I
09:10:03 10 provided training to FDA personnel, as well as FDA
09:10:08 11 asked me to provide the training to international
09:10:11 12 regulators, which I did, so I traveled to several
09:10:15 13 places to provide training to them.

09:10:16 14 Q. Were you paid for that work?

09:10:18 15 A. No, I wasn't paid, but they paid for my
09:10:20 16 travel.

09:10:20 17 Q. Okay. The last time the FDA paid you for
09:10:22 18 any work was six years ago?

09:10:24 19 A. 2011.

09:10:26 20 Q. Okay. Now when you first left the FDA and
09:10:30 21 started getting involved in the work you do now, you
09:10:33 22 were working with a group called NDA Partners?

09:10:36 23 A. Originally, yes.

09:10:37 24 Q. Okay. That's how you got your work;
09:10:40 25 correct?

09:10:40 1 MS. EATON: Object to the form of the
09:10:41 2 question.

09:10:41 3 A. The -- the work of people --

09:10:43 4 Clients would contact NDA Partners who in
09:10:48 5 turn would analyze the request and -- and determine
09:10:52 6 what potential experts they have in their -- I'll call
09:10:56 7 stable --

09:10:57 8 Q. All right.

09:10:58 9 A. -- might -- might be good for that client.

09:11:01 10 Q. And the way that would work is they would
09:11:02 11 get you cases, you'd keep 80 percent of the money and
09:11:05 12 give them 20 percent of the money; is that right?

09:11:07 13 A. Right. I -- I did not receive all of that
09:11:09 14 \$500, but a portion of it.

09:11:10 15 Q. Eighty percent; right?

09:11:12 16 A. I think so, yes, that's the amount.

09:11:14 17 Q. Now you've also done independent work as
09:11:18 18 Ulatowski Consulting.

09:11:19 19 A. Yeah, but very little; I think one or two
09:11:22 20 clients only.

09:11:23 21 Q. Well you used this work, this -- this
09:11:26 22 company, Ulatowski Consulting, you used that vehicle
09:11:30 23 to do work that NDA did not want to be associated
09:11:33 24 with.

09:11:33 25 MS. EATON: Object to the form of the

09:11:34 1 question.

09:11:35 2 A. Well for one reason or another, yes.

09:11:36 3 Q. And that reason being you were a paid
09:11:39 4 consultant to a major tobacco company.

09:11:42 5 A. I -- I took a client, who was a major
09:11:45 6 tobacco company. And that engagement lasted a grand
09:11:49 7 total of one day on site. I guess they didn't like
09:11:52 8 what I told them, so we parted company.

09:11:54 9 Q. NDA told you they did not want to be
09:11:56 10 involved with that work.

09:11:57 11 A. I don't recall the conversation with NDA
09:12:00 12 Partners.

09:12:00 13 Q. Do you recall giving testimony in the I-Flow
09:12:03 14 case -- I-Flow case that NDA did not want you to be
09:12:05 15 involved in that work?

09:12:06 16 A. I don't recall that they didn't want to be
09:12:09 17 involved in that. I just -- I don't recall.

09:12:10 18 Q. Okay. Sitting here today, though, you don't
09:12:15 19 remember that testimony and whether you gave it.

09:12:17 20 A. I remember I-Flow testimony, I just don't
09:12:20 21 remember NDA Partners' position on that.

09:12:22 22 Q. Correct. That's what I mean. You don't
09:12:25 23 know if you did or did not testify that FD -- that NDA
09:12:27 24 told you they did not want to be involved in that
09:12:29 25 work.

09:12:29 1 A. I -- I don't --

09:12:29 2 At this point in time I don't remember.

09:12:32 3 Q. Okay. Then you parted company with NDA and
09:12:35 4 worked with a group called Becker & Associates;
09:12:37 5 correct?

09:12:38 6 A. Yes. I -- I became an employee of Becker &
09:12:42 7 Associates for a period of time.

09:12:44 8 Q. For about four years, three years?

09:12:46 9 A. I don't think it was that long.

09:12:47 10 Q. Okay.

09:12:48 11 A. At least a couple years I think.

09:12:50 12 Q. Okay. And the same essential deal as with
09:12:52 13 NDA, they would find you work and headhunt it for you
09:12:54 14 and provide it to you?

09:12:55 15 MS. EATON: Object to the form of the
09:12:56 16 question.

09:12:56 17 A. Well I was an employee, I was a -- a manager
09:13:00 18 within the company, so clients would come to the
09:13:03 19 company and I would assist them as -- as necessary.

09:13:06 20 Q. Okay. And now you're on your own. You're
09:13:09 21 not having to rely on anybody else to provide work
09:13:12 22 or -- or any of the support or management; correct?

09:13:15 23 A. No. I -- I still have associations with
09:13:18 24 both NDA Partners and what's now called NSF Health
09:13:22 25 Sciences, which used to be called Becker.

09:13:24 1 Q. Okay.

09:13:25 2 A. Becker was purchased by NSF Health Sciences.

09:13:29 3 Q. Is that how you acquired your work in this
09:13:32 4 case?

09:13:32 5 MS. EATON: Object to the form of the
09:13:33 6 question.

09:13:33 7 A. I believe the client --

09:13:34 8 Well I -- I just don't recall. Either the
09:13:37 9 client approached me directly and I then contacted NSF
09:13:41 10 Health Sciences, or NSF Health Sciences was -- was
09:13:45 11 contacted, vice versa.

09:13:45 12 Q. It could have been possible that they
09:13:47 13 contacted you directly; right?

09:13:49 14 A. Clients sometimes do contact me directly.

09:13:51 15 Q. Device manufacturers know to come to you by
09:13:54 16 now.

09:13:54 17 MS. EATON: Object to the form of the
09:13:55 18 question.

09:13:55 19 A. Well as you go along in a -- in any
09:13:58 20 consulting job, you -- you have familiarity with
09:14:01 21 certain clients, sure.

09:14:03 22 Q. Have you had work with 3M before?

09:14:06 23 A. I don't think so. I don't recall. I
09:14:08 24 don't -- I don't believe so.

09:14:09 25 Q. So they -- chances are they might know you

09:14:12 1 through reputation. Do you agree?

09:14:13 2 A. Sure.

09:14:14 3 MS. EATON: Object to the form of the
09:14:15 4 question, calls for speculation.

09:14:19 5 Q. Now since leaving the FDA you've made a lot
09:14:23 6 of money from medical device companies that you were
09:14:26 7 responsible for regulating not too long ago.

09:14:28 8 MS. EATON: Object to the form of the
09:14:29 9 question.

09:14:30 10 A. I've -- I've made an income from doing
09:14:33 11 consulting work, yes.

09:14:34 12 Q. It's what most people would consider to be a
09:14:37 13 lot of money; isn't it, Mr. Ulatowski?

09:14:38 14 A. That's all rel -- relative I suppose.

09:14:41 15 Q. Okay.

09:14:42 16 A. I'm sure Uncle Sam is very happy because
09:14:45 17 half of it goes to him, so --

09:14:48 18 Q. DePuy hip cases, you remember those; right?

09:14:52 19 A. DePuy, yes.

09:14:53 20 Q. Billing was about \$700,000 at the time of
09:14:57 21 the last trial.

09:14:58 22 A. Total billing I don't recall specifically,
09:14:59 23 but that's been a long engagement with several trials.

09:15:02 24 Q. You wouldn't disagree with me that you've
09:15:04 25 testified to Mr. Lanier in that trial that you were

09:15:06 1 paid \$700,000 at the time of trial.

09:15:08 2 A. Perhaps, yes. Perhaps I did.

09:15:10 3 Q. I imagine you get paid for the trial as
09:15:12 4 well.

09:15:13 5 A. Yes.

09:15:13 6 Q. What is that typically like, another hundred
09:15:17 7 grand or --

09:15:17 8 A. Oh, no, no, no. It -- you know, it's my
09:15:20 9 hourly rate, it's how many hours I'm engaged in that
09:15:24 10 trial.

09:15:24 11 Q. How many hours do you think you were engaged
09:15:26 12 in that trial?

09:15:27 13 A. Which trial?

09:15:28 14 Q. The last DePuy trial.

09:15:30 15 A. I couldn't tell you exactly.

09:15:33 16 Q. Okay. But at the end of the day, something
09:15:36 17 close to three quarters of a million dollars from that
09:15:40 18 case.

09:15:41 19 A. Well that case, it -- it's a -- it's an MDL
09:15:44 20 with several trials occurring, rolling over one to
09:15:48 21 another, so it's -- it's been a long engagement.

09:15:50 22 Q. Okay. Now did you testify for DePuy at the
09:15:53 23 trial where the jury found them liable for a billion
09:15:55 24 dollars or the trial where they just found them liable
09:15:58 25 for half a billion dollars, or any one of those?

09:16:01 1 MS. EATON: Object to the form of the
09:16:01 2 question.

09:16:01 3 A. I don't -- I don't recall. I -- I know
09:16:04 4 generally the outcome, but I don't know the awards or
09:16:07 5 anything of that sort. I've been in DePuy trials
09:16:11 6 where defendant has -- has prevailed and trials where
09:16:14 7 they haven't.

09:16:15 8 Q. Okay. Do you do any other work for DePuy?

09:16:18 9 A. No.

09:16:19 10 Q. Okay. Ethicon, do you remember Ethicon?

09:16:22 11 A. Sure.

09:16:23 12 Q. Okay. And your billing for that, probably
09:16:25 13 another half a million?

09:16:27 14 A. Well that's kind of not been a big income
09:16:31 15 area because I haven't done a lot of work in that area
09:16:34 16 in the last year or two.

09:16:35 17 Q. Well my question was: That's been about
09:16:38 18 another half a million though; right?

09:16:39 19 A. I -- I don't recall.

09:16:40 20 Q. Okay. Do you remember testifying at the
09:16:43 21 time of the DePuy hip trial just last year --

09:16:46 22 A. Yes.

09:16:46 23 Q. -- that it was approaching 400,000 at that
09:16:49 24 time?

09:16:49 25 A. I don't recall the statement, but that's --

09:16:51 1 They had at that trial, of course -- my
09:16:54 2 defense attorneys had my vouchers for Ethicon, so if
09:16:56 3 that was the number stated -- that I stated, then --
09:17:00 4 then I'll stand by it.

09:17:01 5 Q. Certainly it doesn't surprise you in an MDL
09:17:04 6 context when you're doing work for these medical
09:17:07 7 manufacturers that your billing could be something
09:17:09 8 like half a million dollars for an MDL like that.

09:17:12 9 MS. EATON: Object to the form of the
09:17:13 10 question, and it's misstating the number of the
09:17:15 11 testimony that he just gave.

09:17:17 12 Q. I'm just saying --

09:17:18 13 Let me withdraw that and address your
09:17:20 14 objection.

09:17:20 15 Irrespective of any case, we've had one with
09:17:24 16 700,000, we've had one approaching 400,000. It would
09:17:26 17 not be a surprise to you to hear that your billing in
09:17:28 18 an MDL was half a million dollars that a medical
09:17:31 19 device manufacturer has given you.

09:17:33 20 A. Well I'm not sure it's -- if it's been in an
09:17:36 21 MDL because the Ethicon engagements have evolved from
09:17:41 22 single cases in states to -- to MDL, so --

09:17:45 23 Q. It wouldn't surprise you in that kind of
09:17:48 24 case that you were paid half a million dollars.

09:17:50 25 A. Total work for Ethicon, if we can frame it

09:17:52 1 that way, I wouldn't be surprised.

09:17:54 2 Q. What about Becton Dickinson. You've done
09:17:58 3 work for them?

09:17:59 4 A. Oh, some time ago.

09:18:00 5 Q. Same kind of work?

09:18:02 6 A. Same kind -- same type of work, yes.

09:18:05 7 Q. Medtronic, you've done work for them?

09:18:07 8 A. Yes.

09:18:08 9 Q. Same kind of work?

09:18:09 10 A. Yes.

09:18:09 11 Q. So it's fair to say we're talking about,
09:18:12 12 since the time you left the FDA, we're well in excess
09:18:15 13 of a seven-figure number that the medical device
09:18:18 14 manufacturers have given you.

09:18:19 15 MS. EATON: Object to the form of the
09:18:20 16 question.

09:18:22 17 A. It's at -- it's at the low range, low of
09:18:25 18 seven.

09:18:26 19 Q. That's something, after having left a career
09:18:28 20 of public service, you're comfortable trading on.

09:18:31 21 MS. EATON: Object to the form of the
09:18:34 22 question.

09:18:34 23 A. Well I don't subscribe to your term "trade."
09:18:37 24 You know, I served a long and -- and well-recognized
09:18:41 25 career at FDA and I'm certainly able and capable and

09:18:45 1 eligible to be a consultant afterward.

09:18:47 2 Q. You provide services for money; right?

09:18:50 3 MS. EATON: Object to the form of the
09:18:51 4 question.

09:18:52 5 A. I have a -- I have a job, yes.

09:18:54 6 Q. You trade what you -- your skills and your
09:18:57 7 presence and your ability to testify, your ability to
09:19:00 8 give opinion, you trade that for a sum of money.

09:19:02 9 MS. EATON: Object to the form of the
09:19:04 10 question.

09:19:04 11 A. I provide a service, a consulting service.

09:19:06 12 Q. Okay. You're not here to testify as an
09:19:10 13 expert in any sort of medical area; are you?

09:19:13 14 A. Could you clarify? Do you mean as a -- as
09:19:19 15 a -- as a physician or as -- as what?

09:19:23 16 Q. Are you going to be --

09:19:25 17 From what I understand you're giving
09:19:26 18 regulatory testimony in this case. That's what your
09:19:29 19 report states; right?

09:19:29 20 A. That's correct. That's the focus of my
09:19:32 21 testimony.

09:19:32 22 Q. Okay. You're not a medical expert.

09:19:33 23 A. I'm not a medical doctor, no.

09:19:35 24 Q. Well there are people who are not doctors
09:19:37 25 who are medical experts; correct?

25

09:19:39 1 A. Well that depends. So what's the question?

09:19:42 2 What's the issue?

09:19:43 3 Q. You have 37 years, did you say, in the FDA?

09:19:45 4 A. That's correct.

09:19:46 5 Q. You've developed --

09:19:47 6 You've probably dealt with a large variety

09:19:48 7 of individuals in the medical device community.

09:19:51 8 A. Right, dealing with many medical -- in

09:19:53 9 quotes, out of quotes -- issues, so you know, I guess

09:19:57 10 I have to understand the parameters of your question.

09:19:59 11 Q. Sure. And what I'm getting to is you've

09:20:01 12 also dealt with people in the industry, medical device

09:20:04 13 industry; correct?

09:20:05 14 A. Yes.

09:20:05 15 Q. Okay. So you've dealt with a broad variety

09:20:08 16 of people of expertise.

09:20:10 17 A. Yes.

09:20:11 18 Q. Some of those people have been doctors.

09:20:12 19 A. Yes.

09:20:13 20 Q. Some of them have not been doctors.

09:20:15 21 A. Correct.

09:20:16 22 Q. Some of the people who are not doctors are

09:20:18 23 people who would classify themselves and hold

09:20:20 24 themselves out as medical experts; correct?

09:20:25 25 MS. EATON: Object to the form of the

09:20:26 1 question.

09:20:27 2 A. Well that's unclear to me, because if one is
09:20:30 3 not a physician with particular expertise, then you
09:20:34 4 have to start to slice and dice.

09:20:36 5 When you say "clinical expert," in what area
09:20:39 6 and what subject? Typically, non-doctors may have
09:20:45 7 expertise in clinical trials, for example.

09:20:48 8 Q. I'm trying to --

09:20:49 9 A. You know, what --

09:20:50 10 I guess I'm trying to --

09:20:51 11 Q. Sure.

09:20:52 12 A. -- still understand your -- your point.

09:20:54 13 Q. What I'm trying to understand is how, when
09:20:56 14 you were asked the same question, you don't hold
09:20:59 15 yourself out or are going to testify as a medical
09:21:01 16 area -- or in any sort of medical areas in I-Flow, you
09:21:04 17 said no. Today is your answer different? Have you --

09:21:07 18 Do you have different expertise today than
09:21:09 19 you did in I-Flow?

09:21:10 20 A. Well I can't say how that question was
09:21:13 21 framed back with I-Flow, but I just don't --

09:21:17 22 I'm just trying to understand the parameters
09:21:19 23 of your question.

09:21:20 24 Q. Sure. I just want you to have the context
09:21:40 25 of that question and your answer. This is your

09:21:42 1 testimony in I-Flow, and I'm going to --

09:21:43 2 MS. EATON: Do you have a copy for me as
3 well?

09:21:46 4 MR. BANKSTON: Yeah, sure.

09:21:46 5 MS. EATON: Thank you.

09:21:47 6 Q. I'm going to hand you a copy of page 20 and
09:21:49 7 I would like you to look at nine -- line 19.

09:21:52 8 A. Okay.

09:21:52 9 MS. EATON: Please pause for one moment, I
09:21:54 10 have to get my glasses.

09:22:10 11 MR. WOJCIECHOWSKI: On the left.

09:22:14 12 MS. EATON: Thank you.

09:22:19 13 Q. All right. On page 20 of this transcript of
09:22:21 14 your testimony in the I-Flow matter --

09:22:23 15 A. Uh-huh?

09:22:23 16 Q. -- it states: "You're not here to testify
09:22:25 17 as an expert in any sort of medical areas; are you?"

09:22:27 18 The answer is: "No, I am not."

09:22:29 19 Do you think that your expertise today is
09:22:33 20 different substantially than your expertise at the
09:22:35 21 time of the I-Flow trial?

09:22:39 22 A. Well I asked about context of the question
09:22:42 23 and I think I'm still trying to understand the
09:22:45 24 parameters of your question, because as I stated here,
09:22:49 25 it's -- as I was asked here is "You are not here" --

09:22:54 1 "here" meaning in that case -- "to testify as an
09:22:56 2 expert in any sort of medical area," and I said, "No,
09:22:59 3 I am not."

09:23:00 4 Q. Okay.

09:23:00 5 A. Well that was that case under those
09:23:03 6 conditions, under that -- that set of evidence
09:23:06 7 with -- given my opinions that I expressed in that
09:23:10 8 case. Today, here we are in July of -- of 2017,
09:23:15 9 different set of documents, different set of
09:23:16 10 experiences. But I have my opinions expressed in my
09:23:19 11 report.

09:23:19 12 Q. Okay. So as opposed to in I-Flow, today in
09:23:23 13 this case with these documents, with your opinions
09:23:25 14 today, are you giving medical opinions?

09:23:28 15 A. I don't have any medical opinions in my
09:23:31 16 report.

09:23:32 17 Q. So that's a no; correct?

09:23:34 18 A. That's --

09:23:35 19 It's as what I stated.

09:23:36 20 Q. I don't -- I don't understand because I
09:23:38 21 asked you if you were giving medical opinions here
09:23:41 22 today in this room -- you, individual, Ulatowski --
09:23:44 23 and you told me about your report, which leads me to
09:23:47 24 suggest that there may be some disconnect between what
09:23:50 25 your report contains and what you plan to testify

09:23:52 1 about. Is that the case?

09:23:53 2 MS. EATON: Can I ask you please not to
09:23:54 3 point at the witness like that?

09:23:55 4 MR. BANKSTON: Okay.

09:23:57 5 A. Depends what questions I'm asked.

09:24:00 6 Q. Okay. Well one of the questions I'm asking
09:24:05 7 you today: Have you formed any medical opinions in
09:24:10 8 this case?

09:24:10 9 A. I don't believe my report has any medical --
09:24:11 10 in quotes, out of quotes -- opinions.

09:24:14 11 Q. I understand your report doesn't have any
09:24:17 12 opinions that are medical. Did you, in working on
09:24:19 13 this case, form any medical opinions?

09:24:20 14 A. All my opinions are expressed in my report.

09:24:23 15 Q. Excellent. Thank you, sir.

09:24:25 16 A. Unless, you know, I guess I'm asked a
09:24:27 17 question that provokes another response.

09:24:29 18 Q. You are not an expert and do not hold
09:24:32 19 yourself out as an expert in the areas of research and
09:24:35 20 design for scientific studies.

09:24:41 21 A. Well it's kind of --

09:24:43 22 It depends. What kind of research studies?
09:24:47 23 In what area? I certainly do have expertise in
09:24:49 24 certain areas.

09:24:55 25 Q. Is that what you're here to talk about

30

09:24:57 1 today? Are you going to be giving any opinions like
09:25:01 2 that?

09:25:01 3 A. I -- none of my --

09:25:04 4 All my opinions are regulatory-focused. I
09:25:08 5 don't provide comment on any particular engineering
09:25:15 6 test methodologies, except in Dr. David I provided an
09:25:19 7 overview comment of his approach in regard to his
09:25:22 8 report. But other than that, certainly I think my
09:25:28 9 report discusses aspects of disinfection of medical
09:25:34 10 equipment which has a methodology to it, so it -- it's
09:25:37 11 kind of -- it depends as to what I'm asked and what's
09:25:43 12 reflected in my report.

09:25:44 13 Q. So your expertise changes from the type of
09:25:47 14 questions you're asked is what you're saying.

09:25:48 15 MS. EATON: Object to the form of the
09:25:49 16 question.

09:25:50 17 A. No. I have expertise in -- in areas that
09:25:53 18 questions may provoke an answer that rely upon my
09:25:57 19 expertise in those areas.

09:25:58 20 Q. Okay. For instance, one of the things that
09:26:00 21 is involved in this case you understand is a surgery;
09:26:02 22 right?

09:26:02 23 A. Is -- is surgery.

09:26:04 24 Q. Correct. Surgeries are involved in this
09:26:06 25 case.

09:26:06 1 A. Yes.

09:26:07 2 Q. Okay. You don't hold yourself out as an
09:26:08 3 expert in any kind of surgical areas such as
09:26:12 4 orthopedic surgery.

09:26:13 5 A. No.

09:26:13 6 Q. You're not going to be giving the jury an
09:26:16 7 opinion within a reasonable degree of medical
09:26:20 8 certainty that there is valid scientific evidence of
09:26:22 9 probable health benefits from the use of the Bair
09:26:25 10 Hugger in orthopedic surgeries.

09:26:36 11 A. Well I -- I allude to that in my report in
09:26:41 12 regard to benefit and risk, so inasmuch as my report
09:26:46 13 touches upon benefit aspects and -- and risk, which is
09:26:50 14 reflected in clinical studies, published data, my
09:26:55 15 report is what it is.

09:26:56 16 Q. Well right. And that report does not
09:26:58 17 contain an opinion to a reasonable degree of medical
09:27:02 18 certainty that there is valid scientific evidence of a
09:27:05 19 probable health benefit from the use of the Bair
09:27:08 20 Hugger in orthopedic surgeries.

09:27:11 21 A. In orthopedic surgeries. Well I guess I
09:27:13 22 have to look at my report because I do discuss valid
09:27:16 23 scientific evidence and I do discuss the relationship
09:27:21 24 with certain data submitted to FDA as consisting of
09:27:25 25 valid scientific evidence. So again, it's a -- it's

09:27:28 1 the question, it's the specifics that you may ask.

09:27:30 2 Q. Well let's dive into that. In terms of you
09:27:33 3 giving opinions that there is, within a reasonable
09:27:35 4 degree of medical certainty, valid scientific evidence
09:27:38 5 of probable health benefits from the use of the Bair
09:27:40 6 Hugger in orthopedic surgeries, what is that
09:27:43 7 scientific evidence?

09:27:43 8 A. Well it wouldn't be -- let me clarify. It
09:27:46 9 wouldn't be --

09:27:48 10 I think in my report as I characterized it,
09:27:51 11 again, from a regulatory point of view, it was valid
09:27:54 12 scientif -- scientific evidence applied to the Bair
09:27:58 13 Hugger in regard to its regulatory significance, not
09:28:03 14 medical significance.

09:28:03 15 Q. Okay. So in other words, you may be giving
09:28:06 16 us opinions about whether or not the defendant
09:28:10 17 complied with the regulatory scheme that you oversaw
09:28:12 18 during your many years at the FDA, but at the same
09:28:15 19 time you will not be giving an opinion, a medical
09:28:18 20 opinion, about the benefits of a Bair Hugger in
09:28:20 21 orthopedic surgery. Is that fair?

09:28:23 22 A. Generally, no.

09:28:24 23 Q. Okay. Just because that may be a little --
09:28:28 24 on the record, are you -- are you disagreeing and
09:28:31 25 saying you will be giving medical opinions on the

09:28:33 1 benefits of the Bair Hugger in orthopedic surgery or
09:28:35 2 you will not be giving those medical opinions?

09:28:37 3 A. I will not. But it depends on -- again, on
09:28:41 4 the question asked and whether it touches upon
09:28:43 5 expertise I may have.

09:28:44 6 Q. Okay. Well in terms of the question I just
09:28:46 7 asked and when I asked you for the scientific
09:28:50 8 evidence, do you have a medical opinion about the
09:28:52 9 benefits of the Bair Hugger in orthopedic surgeries?

09:28:57 10 A. No. I've refer -- referenced other groups
09:29:02 11 and persons who have commented on that as a basis for
09:29:06 12 certain opinions I have.

09:29:06 13 Q. And there are other experts in this case, I
09:29:08 14 assume you know from reading your reports, who have
09:29:11 15 given medical opinions and are giving medical opinions
09:29:14 16 on behalf of 3M; correct?

09:29:15 17 A. Yes, I know that.

09:29:16 18 Q. Okay. You would agree with me that in terms
09:29:19 19 of whether the Bair Hugger has medical benefit in an
09:29:22 20 orthopedic surgery, witnesses such as that are far
09:29:26 21 better addressed to answer that question than somebody
09:29:30 22 with your lack of medical training.

09:29:30 23 MS. EATON: Object to the form of that
09:29:32 24 question.

09:29:32 25 A. I would -- I would defer to other defendant

09:29:35 1 experts that have more direct experience in that
09:29:38 2 regard.

09:29:39 3 Q. Okay. By the same token, you will not be
09:29:43 4 giving the jury an opinion to a reasonable degree of
09:29:46 5 medical certainty about the degree of medical risk
09:29:47 6 from the use of the Bair Hugger in orthopedic
09:29:49 7 surgeries.

09:29:50 8 A. Medical risk?

09:29:52 9 Q. Correct.

09:29:53 10 A. I would defer to other defendant experts in
09:29:56 11 regard to that.

09:29:56 12 Q. You don't hold yourself out as an expert in
09:29:59 13 statistics or statistical analysis; correct?

09:30:01 14 A. No, I do not.

09:30:04 15 Q. Okay. Now before you accept any litigation
09:30:07 16 work, do you agree with me you have to make sure you
09:30:10 17 don't have any conflicts of interest relating to the
09:30:12 18 work?

09:30:12 19 A. That's correct.

09:30:13 20 Q. I'm wondering: Did you contact anybody at
09:30:17 21 the FDA, like an ethics officer, about your testimony
09:30:19 22 in this case?

09:30:20 23 A. I have.

09:30:20 24 Q. Okay. And can you tell me --

09:30:21 25 A. In this case?

09:30:22 1 Q. Yes.

09:30:23 2 A. Not in this case, but in performance of my
09:30:26 3 consulting duties I contacted the Ethics Office a
09:30:30 4 couple, three times to understand their parameters of
09:30:33 5 what clients can engage me, what data and information
09:30:37 6 I can rely upon to understand where to draw potential
09:30:41 7 lines where I -- I cannot have input.

09:30:45 8 Q. Now in some prior cases you have
09:30:47 9 specifically contacted the Ethics Office to discuss
09:30:50 10 whether your work in that specific case was
09:30:52 11 appropriate; correct?

09:30:53 12 A. Well as I said, I contacted the Ethics
09:30:55 13 Office. It -- it may have been as a result of a
09:30:58 14 particular engagement, but I think the questions were
09:31:00 15 general in nature and not specific.

09:31:02 16 Q. Okay. What is your understanding of the
09:31:05 17 parameters in which you can testify for a product that
09:31:09 18 was under the purview of the FDA while you were there?

09:31:13 19 A. Well one of the key responses I have, I
09:31:17 20 still have the documentation, is if you're relying
09:31:21 21 upon information produced in the litigation and you're
09:31:26 22 not relying upon any information that you took from
09:31:30 23 FDA or you know from behind the scenes at FDA, then
09:31:36 24 you're more than -- than capable of engaging in that
09:31:39 25 litigation.

09:31:39 1 Q. Then you would also agree with me to the
09:31:42 2 converse. If you do possess significant information
09:31:45 3 from the time at your FDA, if you had direct
09:31:47 4 involvement in the regulation of the product, then it
09:31:50 5 may not be appropriate for you to testify.

09:31:52 6 MS. EATON: Object to the form of the
09:31:53 7 question. And you used a different verb than he did,
09:31:56 8 so it misstates his testimony.

09:31:58 9 A. Well again, the -- the directive from the
09:32:01 10 Ethics Office was: Where -- what -- what information
09:32:06 11 are you relying upon? Is it from production in the
09:32:08 12 litigation? You can't testify to anything you heard
09:32:14 13 or discussions at FDA. You can't rely upon any
09:32:19 14 documentation that you may have from FDA. And that
09:32:22 15 was really the parameters directed to me.

09:32:24 16 Q. Okay. Let me ask you this: If you had a
09:32:26 17 product that a manufacturer approached you to give
09:32:29 18 litigation expert testimony on and you had direct
09:32:32 19 involvement in agency actions relating to that
09:32:35 20 product, is it ethical for you to testify?

09:32:37 21 A. I believe so.

09:32:38 22 Q. Okay. Under what circumstances would you
09:32:42 23 have to be involved with the product for it not to be
09:32:44 24 ethical to testify?

09:32:45 25 A. Well there's actually some initial

09:32:50 1 revolving-door restrictions where I -- I couldn't
09:32:54 2 participate for a year, two years; of course, those
09:32:56 3 have long expired. And so, otherwise, then it becomes
09:33:02 4 much more open as far as participation.

09:33:05 5 Q. Well I guess my question is: In coming to
09:33:10 6 decide whether it's appropriate or not, whether it's
09:33:12 7 permitted or not to testify in a case, you would agree
09:33:16 8 with me that there is some question -- some focus is
09:33:20 9 given on the issue of whether you had direct
09:33:21 10 involvement in the regulation of that product.

09:33:26 11 A. Well, I mean, what's your question?

09:33:28 12 Q. My question is: In deciding to work on
09:33:30 13 cases, does it matter if you had substantial
09:33:32 14 involvement in the product's regulation?

09:33:35 15 A. Well I -- I consider that. I consider
09:33:39 16 fundamentally what I -- what I recall, what I
09:33:43 17 remember, what -- what impact I had, how routine was
09:33:47 18 it, so I -- I consider that, but it hasn't necessarily
09:33:54 19 prevented my engagement.

09:33:55 20 Q. Okay. That --

09:33:56 21 So when you're thinking about whether it's
09:33:58 22 ethical to take a client, one of the things that you
09:34:01 23 considered is whether you had any direct involvement
09:34:03 24 in the product during its regulatory period.

09:34:06 25 A. Right. And perhaps whether I'm -- I'm

09:34:09 1 better as a fact witness rather than a -- you know, an
09:34:13 2 expert witness.

09:34:13 3 Q. Why do you consider that?

09:34:18 4 A. Just -- just to understand whether -- to
09:34:23 5 what degree I -- I remember any circumstance. Because
09:34:25 6 I'm always asked, "Well, what do you recall about this
09:34:29 7 while you were at FDA? What -- what discussions do
09:34:31 8 you recall? What background do you" -- did -- you
09:34:33 9 know, "What decisions did you make?" And at this
09:34:36 10 point in time, basically I've forgotten whatever has
09:34:41 11 occurred with Bair Hugger while I was FDA -- at FDA,
09:34:43 12 so --

09:34:45 13 And then I turn to, well, I'm going to rely
09:34:47 14 upon whatever is produced in this litigation because
09:34:50 15 otherwise I'm not going to remember anything.

09:34:52 16 Q. Okay.

09:34:53 17 MR. BANKSTON: Object as non-responsive.

09:34:54 18 Q. My question more goes to there are things
09:34:57 19 you consider when deciding if you can ethically take
09:35:00 20 on a client, and one of those things you told me you
09:35:02 21 consider is the extent of your direct involvement in
09:35:05 22 the product. Why is your direct involvement in the
09:35:08 23 product relevant to whether you can ethically take a
09:35:12 24 case?

09:35:13 25 A. It's just -- it's just a matter of fact.

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09:35:16 1 Was -- was I involved? Did I sign anything? Was I
09:35:19 2 engaged in any way, shape or form? I think to help
09:35:23 3 understand -- in understanding my role how to approach
09:35:28 4 the -- the documentation in the litigation, knowing
09:35:34 5 that -- trying to set the parameters of why I can't
09:35:37 6 talk about this because this isn't part of the
09:35:39 7 production, this is something that no one can be made
09:35:42 8 aware of even if I knew something, so it's just to
09:35:45 9 understand, trying to take a walk down Memory Lane in
09:35:50 10 regard to the product.

09:35:52 11 Q. You would agree with me that if you had ever
09:35:53 12 made agency decisions directly about a product, had
09:35:56 13 been the person responsible for making those
09:35:59 14 decisions, it would not be appropriate for you to
09:36:01 15 testify about that product because of a conflict of
09:36:03 16 interest.

09:36:03 17 MS. EATON: Object to the form of the
18 question, --

19 A. Not if the subject --

09:36:07 20 MS. EATON: -- assumes legal standards and
09:36:10 21 facts not in evidence.

09:36:13 22 A. Well you've made a statement. I -- it's
09:36:14 23 clear that, from my direction from the Ethics Office,
09:36:17 24 I can be engaged in this type of litigation. I'll
09:36:20 25 leave it at that.

09:36:20 1 Q. "This type of litigation." You mean
09:36:22 2 litigation in which there are medical devices?

09:36:25 3 A. And -- and if I have -- have had
09:36:27 4 involvement. And -- and it's frequently the case that
09:36:31 5 FDA individuals are engaged in topic areas where they
09:36:35 6 were involved at FDA, --

09:36:36 7 Q. Okay.

09:36:36 8 A. -- so --

09:36:37 9 Q. Okay. So --

09:36:37 10 I guess that takes us back to, when deciding
09:36:40 11 if you can ethically work on a case, you don't have to
09:36:43 12 consider whether you have substantial involvement.

09:36:46 13 MS. EATON: Object to the form of the
09:36:47 14 question.

09:36:47 15 A. Perhaps I don't. It's just an exercise I go
09:36:51 16 through to try and recollect circumstances, but
09:36:54 17 frequently it's fruitless because I was involved with
09:36:57 18 so many things that, you know, I just don't know the
09:36:59 19 specifics other than what's produced in the -- in the
09:37:02 20 litigation.

09:37:02 21 Q. Well one of the things you're going to
09:37:04 22 testify about here today is that a 510(k) decision is
09:37:08 23 in some manner determination of safety; correct?

09:37:11 24 A. My opinion is that --

09:37:14 25 Well, it reads as it reads, that safety and

09:37:17 1 effectiveness are considerations in a 510(k)
09:37:20 2 evaluation.

09:37:20 3 Q. Okay. If you were to have made a 510(k)
09:37:25 4 decision on a product and then you were later asked
09:37:29 5 in -- in a litigation context whether that product was
09:37:32 6 dangerous or not, you would agree that invokes a
09:37:35 7 potential conflict.

09:37:37 8 A. I'm not so sure about that, because the
09:37:40 9 510(k) process is a -- is a moment in time based upon
09:37:48 10 documentation at a point in time, and -- and once a
09:37:52 11 product is then marketed, things can happen. Things
09:37:57 12 can happen during manufacturing, things can happen
09:38:00 13 that are only revealed through clinical use, so
09:38:03 14 the -- the circumstances of a product may change over
09:38:06 15 time. So a decision can be made on a 510(k) and a
09:38:11 16 good decision can be made on a 510(k) which may later,
09:38:14 17 because of other facts and circumstances, may -- may
09:38:17 18 alter the circumstances of the safety and
09:38:19 19 effectiveness of that product.

09:38:21 20 Q. If the plaintiff in a lawsuit alleged that a
09:38:24 21 510(k) was improperly granted and that a product
09:38:27 22 should not have been cleared and you were one of the
09:38:30 23 people involved in that process, in that hypothetical
09:38:33 24 situation there's a conflict there; isn't there?

09:38:36 25 A. I don't think so. I'd have to look at the

09:38:38 1 facts in that instance to see what -- what the
09:38:40 2 argument is and -- and evaluate that.

09:38:44 3 Q. If you were asked in that kind of case, "Was
09:38:48 4 the FDA decision rightfully or wrongfully granted?"
09:38:51 5 in coming to that decision, if you arrived at the
09:38:53 6 decision that it was wrongfully granted, that would be
09:38:56 7 an indictment of yourself if you had been the person
09:38:58 8 who had approved it; correct?

09:38:59 9 MS. EATON: Object to the form of that
09:39:00 10 question.

09:39:06 11 A. If a certain fact --

09:39:09 12 The answer is -- is perhaps, because in
09:39:11 13 certain circumstances certain facts come to my
09:39:13 14 attention that, upon retrospect, may affect my opinion
09:39:21 15 on the basis for the finding of equivalence. I did
09:39:26 16 so, for example, in an I-Flow case, looking at certain
09:39:28 17 interactions of FDA personnel with the company in
09:39:33 18 rendering an opinion that, well, if -- if we really
09:39:34 19 had thought about that or asked about that, we may
09:39:39 20 have come up with a different decision. So -- so
09:39:42 21 those opportunities present themselves, but rarely.

09:39:45 22 Q. Okay. But in this case you don't have that
09:39:47 23 problem -- well let me back up.

09:39:48 24 You understand in this case and from the
09:39:52 25 report of Yadin David that there is the allegation

09:39:54 1 that this product should not have cleared 510(k), both
09:39:58 2 as the Bair Hugger 500 and 750 series.

09:40:02 3 MS. EATON: Object to the form of the
09:40:02 4 question.

09:40:03 5 A. Well I don't think he comes out and says
09:40:06 6 that directly. I think he says the -- the process
09:40:08 7 was -- was troubling in one respect or another. Of
09:40:11 8 course I found otherwise, but -- but I -- I just -- I
09:40:17 9 just disagree with his perspective on the 510(k).

09:40:21 10 Q. Sure. We'll get to all of that.

09:40:23 11 A. Sure.

09:40:25 12 Q. All I'm trying to set up -- and I'm going to
09:40:26 13 use your word -- is you understand Dr. David is
09:40:28 14 critical in that he calls the regulatory history of
09:40:31 15 this product alarming; correct?

09:40:32 16 MS. EATON: Object to the form of the
09:40:33 17 question. That's not what he said.

09:40:34 18 A. Well I mean "troubling" was --

09:40:35 19 Q. "Troubling," I'm sorry, your word was
09:40:37 20 "troubling." Let's do it again, put it on the record
09:40:41 21 again.

09:40:41 22 You understand that Dr. David in his report
09:40:41 23 criticizes the regulatory process as troubling.

09:40:44 24 A. Yes.

09:40:45 25 Q. Okay. But in this case we don't have the

09:40:48 1 kind of conflict we were just talking about because
09:40:50 2 you were never involved in any kind of 510(k) approval
09:40:53 3 for this product; right?

09:40:54 4 A. Clearance for the product, no.

09:40:56 5 Q. And again, let me go ahead and make that
09:40:59 6 clear for the record. And please keep correcting me
09:41:02 7 if I use the wrong word today because eventually you
09:41:06 8 will probably drill it into my head. But in terms --
9 we don't --

09:41:08 10 In this case we don't have the same conflict
09:41:10 11 we had just been talking about where you may have a
09:41:12 12 plaintiff alleging something about 510(k) when you
09:41:15 13 were involved in it. In this case you had no
09:41:17 14 involvement, did -- made no approvals in 510(k);
09:41:19 15 correct?

09:41:20 16 A. 510(k) clearances, yes.

09:41:22 17 Q. 510(k) clearances.

09:41:23 18 A. Right.

09:41:24 19 Q. Okay. So the poten --

09:41:24 20 According to you, there is no potential
09:41:26 21 conflict because there is no approval letter from
09:41:31 22 Timothy Ulatowski regarding the Bair Hugger.

09:41:32 23 Or excuse me.

09:41:32 24 MS. EATON: Object to the form of the
09:41:33 25 question.

45

1 MR. BANKSTON: Say that again. I think I'm
09:41:34 2 going to get it.

09:41:34 3 MS. EATON: That wasn't the only reason I
09:41:36 4 objected to the form --

5 MR. BANKSTON: I'll let you get --

09:41:37 6 MS. EATON: -- but that was one.

09:41:38 7 MR. BANKSTON: I'll let you get your other
09:41:40 8 objection in in a second here.

09:41:42 9 Q. In this case we don't have this kind of
09:41:45 10 conflict because there is no clearance letter from Tim
09:41:49 11 Ulatowski about the Bair Hugger.

09:41:49 12 MS. EATON: Object to the form of the
09:41:50 13 question.

09:41:50 14 A. Well there is no letter from Timothy
09:41:53 15 Ulatowski. I --

09:41:54 16 You characterize that as a conflict or
09:41:55 17 whatever. I -- I -- I don't agree with that, --

09:41:57 18 Q. Okay.

19 A. -- but -- but --

09:41:57 20 Q. Wait a minute. Hold on one second. Let me
09:42:00 21 just back up because I think I may be misunderstanding
09:42:03 22 your testimony. I thought that we had come to the
09:42:06 23 realization that if there was a plaintiff alleging a
09:42:09 24 problem with the 510(k) process and an FDA employee
09:42:12 25 had been the person responsible for that 510(k)

09:42:14 1 decision, that there could be a potential conflict

09:42:17 2 there. Do you agree with that?

09:42:19 3 A. I don't think we came to that conclusion.

4 Q. Okay. Can you --

09:42:21 5 A. I didn't state that.

09:42:21 6 Q. Okay. And that --

09:42:23 7 I just want it clear on the record.

09:42:23 8 A. Yeah.

09:42:23 9 Q. You don't agree that there -- there's any

09:42:25 10 potential conflict now.

09:42:26 11 A. I don't believe there's a conflict because

09:42:30 12 each case stands -- is -- is -- is independent, each

09:42:33 13 case is based upon productions in that particular

09:42:36 14 case. I rely upon the production or rely upon the

09:42:39 15 facts in the particular case.

09:42:40 16 Q. And I'm not so much concerned about anything

09:42:43 17 else that happens be -- beyond the date you're

09:42:46 18 retained or -- or let's keep it hypothetical -- beyond

09:42:51 19 an FDA employee -- former FDA employee is retained; in

09:42:52 20 other words, the materials they see and what they do.

09:42:54 21 I'm talking about the ethical decision to have

09:42:57 22 engagement. And what I want to understand is if

09:43:00 23 there's a former FDA employee who made a decision on

09:43:02 24 the 510(k) and then there is a plaintiff who is

09:43:04 25 alleging a problem with that decision, that if that

09:43:08 1 employee was to come to a decision that that 510(k)
09:43:11 2 was granted wrongfully, they would be criticizing
09:43:14 3 themselves.

09:43:15 4 MS. EATON: Object to the form of the
09:43:16 5 question, and also object to any attempt to tie what
09:43:18 6 you just said to what's expressed in Dr. David's
09:43:22 7 reports.

09:43:25 8 MR. BANKSTON: The basis, like the legal
09:43:25 9 basis though. For that little bit, what was the legal
09:43:28 10 basis?

09:43:28 11 MS. EATON: Let me read it.

09:43:29 12 MR. BANKSTON: If we kind of keep it
09:43:31 13 confined to legal bases instead of talking, that would
09:43:35 14 be great.

09:43:35 15 MS. EATON: I think I've been doing a great
09:43:38 16 job here with your questions.

09:43:38 17 MR. BANKSTON: You've been doing -- you've
09:43:39 18 been doing a lot better than the last people in this
09:43:41 19 case. You know me, and I'm very policing about that.

09:43:42 20 MS. EATON: And your -- yeah. And your
09:43:44 21 questions give me a lot to object to.

09:43:46 22 MR. BANKSTON: Right. With -- consistent
09:43:47 23 with the federal rules and not speaking objections.
09:43:50 24 Let's keep it clean.

09:43:51 25 MS. EATON: I'm trying.

09:43:53 1 MR. BANKSTON: Actually, I understand that
09:43:53 2 you're giving it an effort and that's --

09:43:55 3 When you don't, I'm going to go ahead and
09:43:56 4 remind you. Just like every time I say "clearance" or
09:43:59 5 "approval" --

09:44:00 6 MS. EATON: I need -- I need a second to
09:44:01 7 read this or I'm not going to be able to give you
09:44:03 8 your --

09:44:03 9 MR. BANKSTON: Okay. Legal objection.

09:44:04 10 MS. EATON: Yeah.

09:44:06 11 MR. BANKSTON: Okay.

09:44:26 12 MS. EATON: Objection to the hypothetical.
09:44:28 13 And I don't understand that Dr. David gave any opinion
09:44:30 14 that the FDA did something wrong. I understand --

09:44:32 15 MR. BANKSTON: Hold -- hold -- hold it.

09:44:33 16 MS. EATON: You asked me why I said what I
09:44:35 17 said, and what I said is --

09:44:36 18 MR. BANKSTON: No. I asked for your legal
09:44:37 19 objection and for there not to be speaking objections.

09:44:39 20 MS. EATON: Right.

21 MR. BANKSTON: I'm going to ask --

09:44:40 22 MS. EATON: My legal objection is I think
09:44:41 23 you mischaracterized Dr. David's report and I think
09:44:43 24 your question is an incomplete hypothetical.

09:44:45 25 MR. BANKSTON: Okay. There we go. That's

09:44:46 1 how we do that.

09:44:47 2 MS. EATON: I don't need your instruction
09:44:48 3 about how to practice law. Thank you.

09:44:50 4 MR. BANKSTON: I think you do. Let's not --

09:44:52 5 MS. EATON: We can continue.

09:44:52 6 MR. BANKSTON: Let's not -- let's not do --

09:44:53 7 Let's put it on the record right now that I
09:44:55 8 have now officially asked counsel multiple times
09:44:58 9 please do not have speaking objections in this
09:44:59 10 deposition.

09:45:00 11 MS. EATON: You asked me the basis of my
09:45:03 12 form objection.

09:45:03 13 MR. BANKSTON: I've asked that --

09:45:03 14 Excuse me, ma'am. What is going on here? I
09:45:06 15 feel like there's like just absolute anarchy right
09:45:10 16 now. I'm in the middle of speaking to a court
09:45:11 17 reporter to put something on the record and you just
09:45:13 18 flat out interrupted me with more speaking, and in a
09:45:18 19 deposition we do not need speaking. So I know this is
09:45:18 20 a tense situation, I know you're going to want to be
09:45:22 21 motivated to speak and make commentary on the record.
09:45:24 22 I don't think it's appropriate. I've said that in the
09:45:26 23 last expert deposition I was in. I have in this case
09:45:29 24 brought a motion, successfully, on this issue against
09:45:32 25 counsel. Let's not do it. It's not hard. It's not

09:45:36 1 difficult at all to just give a legal objection.

09:45:38 2 So from this moment forward, I'd please

09:45:41 3 appreciate it if we didn't have any more commentary,

09:45:44 4 we just had legal objections. Is that agreeable?

09:45:45 5 MS. EATON: Mr. Bankston, it is, except when

09:45:47 6 you ask me for the basis of my objection, I will

09:45:51 7 answer your question, and that's what I was just

09:45:52 8 doing.

09:45:52 9 MR. BANKSTON: Okay.

09:45:53 10 BY MR. BANKSTON:

09:46:15 11 Q. You signed a number of -- in fact let me --

09:46:19 12 Because so much has elapsed between that and

09:46:22 13 the objection, we'll withdraw that last question. I

09:46:25 14 know there's a question, but --

09:46:25 15 A. Good, because I've lost it entirely.

09:46:27 16 Q. Believe me, I have no idea what that

09:46:31 17 question was. I know, that's kind of the problem.

09:46:34 18 When you were working at the FDA, there are

09:46:34 19 documents relating to the Bair Hugger you signed.

09:46:38 20 A. Well --

09:46:38 21 Q. Let me -- and let me be more specific.

09:46:41 22 Enforcement actions.

09:46:42 23 A. It's not an enforcement action.

09:46:44 24 Q. Okay. And -- and this may be my bad

09:46:47 25 terminology. When a warning letter is issued, what

09:46:50 1 kind of action is that?

09:46:51 2 A. An advisory action.

09:46:52 3 Q. Okay. And -- and an advisory action is --

09:46:56 4 Those are actions that you had

09:46:57 5 responsibility at during what approximate time of your

09:47:00 6 tenure?

09:47:00 7 A. 2003 to 2011.

09:47:02 8 Q. Okay. During that entire period of that

09:47:04 9 space, you were involved in advising companies if they

09:47:09 10 were perhaps in violation or potential violation of

09:47:12 11 regulations.

09:47:13 12 A. Correct.

09:47:13 13 Q. Okay. One of the people that you made an

09:47:17 14 advisory action to is your current client.

09:47:22 15 A. Correct.

09:47:23 16 Q. That --

09:47:25 17 And that advisory letter concerned adverse

09:47:28 18 events.

09:47:29 19 A. Correct.

09:47:30 20 Q. Those adverse events, those were burns;

09:47:33 21 right?

09:47:33 22 A. That was associated, yes. Right.

09:47:36 23 Q. And there were burns that had not been

09:47:40 24 properly reported by the company.

09:47:41 25 A. There were reporting issues that were

09:47:43 1 observed.

09:47:44 2 Q. You're familiar with what I say when I say
09:47:47 3 MDR?

09:47:47 4 A. Correct.

09:47:48 5 Q. Can you explain to the jury real quick what
09:47:50 6 an MDR is.

09:47:51 7 A. Medical device report. It's a report made
09:47:54 8 to FDA by manufacturers, by healthcare facilities, by
09:47:59 9 importers related to deaths or serious injuries
09:48:02 10 that -- or malfunctions that -- that may be related or
09:48:06 11 associated with a medical device.

09:48:08 12 Q. That may be related; correct?

09:48:09 13 A. Correct.

09:48:10 14 Q. Okay. In other words, if a -- a
09:48:13 15 manufacturer has information in its possession that a
09:48:16 16 device is potentially involved in an adverse event,
09:48:20 17 under certain circumstances that has to be reported.

09:48:23 18 A. If there's reasonable evidence to that fact,
09:48:25 19 yes.

09:48:25 20 Q. Okay. In the case of your advisory letter,
09:48:30 21 there were adverse events that legally should have
09:48:33 22 been reported to the FDA but were not reported to the
09:48:35 23 FDA by Arizant; correct?

09:48:38 24 A. As I recall, there were observations related
09:48:40 25 to late reports or non-reports, yes. A few.

09:48:46 1 Q. You would agree with me that the bulk of
09:48:49 2 your opinions in this case focus on FDA regulations,
09:48:51 3 FDA procedures such as the 510(k) clearance process,
09:48:55 4 FDA communications, defendants' compliance with
09:49:00 5 regulatory duties, these are the general things you're
09:49:04 6 testifying about.

09:49:04 7 A. That's the bulk of it, although there's a --
09:49:08 8 a -- I'll call it a smattering of -- of expertise I --
09:49:13 9 I offer in regard to a particular area of expertise I
09:49:16 10 have in regard to disinfection, sterilization for
09:49:19 11 example.

09:49:19 12 Q. Okay. For my next series of questions I
09:49:22 13 want to limit us to the parts and opinions of your
09:49:24 14 report that deal with the 510(k) process. Okay?

09:49:28 15 A. Okay.

09:49:29 16 Q. From the way I understand it, 510(k) is a
09:49:32 17 determination by the FDA that a product being offered
09:49:36 18 in the application is substantially equivalent to a
09:49:40 19 previously-legally-marketed product.

09:49:42 20 A. That's correct.

09:49:43 21 Q. Okay.

09:49:43 22 A. That is also Class II and subject to legal
09:49:47 23 marketing, as you said.

09:49:49 24 Q. Okay.

09:49:49 25 A. For classification number.

09:49:51 1 Q. You would agree that your opinions in this
09:49:53 2 case both implicate the 510(k) clearance process in
09:49:56 3 general and with respect to Bair Hugger specifically.

09:49:59 4 A. Correct.

09:49:59 5 Q. Okay. You would also say that the 510(k)
09:50:05 6 process speaks to or relates to safety and efficacy.

09:50:10 7 A. Yes. It must.

09:50:11 8 Q. Okay. In fact, you have testified before
09:50:17 9 and I believe you'll be testifying today that 510(k)
09:50:19 10 clearance is a determination of safety and
09:50:21 11 effectiveness.

09:50:22 12 A. No, I am not.

09:50:23 13 Q. Okay. That's not going to be your opinion
09:50:25 14 today.

09:50:25 15 A. No.

09:50:26 16 Q. Okay. I notice your report provides a
09:50:31 17 narrative description of the FDA processes for
09:50:33 18 regulating medical devices; is that correct?

09:50:35 19 A. Correct.

09:50:36 20 Q. It has an overview of forced-air warming
09:50:40 21 devices generally?

09:50:41 22 A. Generally, yes.

09:50:42 23 Q. Okay. It has -- discusses a history of
09:50:45 24 Arizant's 510(k) submissions?

09:50:47 25 A. Right, to the degree that I could discover

09:50:49 1 that on FDA's website.

09:50:50 2 Q. Okay. Now all of those things we just
09:50:57 3 talked about, these opinions that you hold, you will
09:50:59 4 agree with me multiple federal courts have excluded
09:51:03 5 those opinions as improper.

09:51:04 6 MS. EATON: Object to the form of the
09:51:05 7 question.

09:51:05 8 A. No, that's incorrect.

09:51:07 9 Q. Okay. Do you remember in --

09:51:08 10 You remember the Bellew versus Ethicon case?

09:51:11 11 A. Well let me -- let me try and clarify what I
09:51:16 12 just said. I know that certain judges have excluded
09:51:21 13 testimony on 510(k)s simply because they -- they don't
09:51:25 14 want to talk about federal regulations and 510(k)s.
09:51:28 15 It's not me, it's not my report, it's just an overall
09:51:32 16 decision that we're not going to talk about this
09:51:35 17 topic.

09:51:36 18 Q. You don't believe that federal courts have
09:51:38 19 stated that you have stated the law incorrectly?

09:51:40 20 A. Well if you let me finish -- you jumped in.

09:51:44 21 The other half has been in a case people
09:51:49 22 have brought up, Medtronic/Lohr, for example, and the
09:51:54 23 Supreme Court's decision on PMAs, premarket approval
09:51:58 24 applications versus 510(k)s, although the fact is that
09:52:03 25 I've recognized the regulatory standard for PMAs

09:52:06 1 versus 510(k)s, which is different, but nonetheless
09:52:11 2 for a 510(k), as I state in this report, the elements
09:52:15 3 of safety and effectiveness factor into every 510(k)
09:52:18 4 review, and -- and it must, as noted by regulation and
09:52:21 5 statute.

09:52:21 6 Q. Now multiple federal courts have said, in
09:52:24 7 regard to your testimony, the kind of opinions that
09:52:26 8 you give about 510(k), have said the 510(k) clearance
09:52:30 9 process does not speak to safety and effectiveness,
09:52:33 10 disagreeing with you. Do you remember that?

09:52:35 11 A. Well I -- I think we --

09:52:37 12 I'm not a lawyer so I can't speak to the
09:52:39 13 Supreme Court's specific decision, any judge's
09:52:43 14 particular evaluation of -- of, for example,
09:52:46 15 Medtronic/Lohr or the Supreme Court's dicta in regard
09:52:49 16 to their decision that might illuminate their decision
09:52:53 17 further, but what I'm providing in my report in this
09:52:58 18 case is to make it clear that, as FDA points out,
09:53:04 19 safety and effectiveness factors into every 510(k)
09:53:07 20 review. And I provide ample basis for that.

09:53:09 21 Q. Okay.

09:53:10 22 A. Now understanding and recognizing, as I do
09:53:13 23 in my report, the PMA standard is not the same as the
09:53:16 24 510(k) standard. The PMA standard is a determination
09:53:19 25 of safety and effectiveness.

09:53:20 1 Q. Uh-huh.

09:53:21 2 A. 510(k) standard is substantial equivalence.

09:53:25 3 So I -- I recognize that, that's certainly the case,

09:53:29 4 but now you have to burrow into how do you determine

09:53:31 5 substantial equivalence, what factors enter into that

09:53:34 6 decision, and so that's where my comments arise.

09:53:38 7 Q. Okay. My -- my question was in --

09:53:40 8 Well I'm sure we'll be talking about a lot

09:53:43 9 of this stuff, so I don't mean to dive too quickly

09:53:46 10 into some of this, but my question was simply: You

09:53:48 11 recognize that multiple federal courts have said that

09:53:50 12 you were wrong, that 510(k) does not relate to safety

09:53:53 13 and effectiveness.

09:53:54 14 A. Well I'm not sure they said it in those

09:53:56 15 terms. I think they are recognizing that the standard

09:53:59 16 is different between PMAs and 510(k)s.

09:54:02 17 Q. Would you -- would you be of the opinion

09:54:05 18 that a 510(k) clearance is equivalent to a finding of

09:54:08 19 non-negligent design?

09:54:11 20 A. Well that sounds like -- like a legal --

09:54:13 21 legal finding. I'm not a lawyer, so I couldn't

09:54:16 22 comment on that.

09:54:16 23 Q. That's an opinion you gave in NexGen though;

09:54:19 24 correct?

09:54:19 25 MS. EATON: Object to the form of the

09:54:20 1 question.

09:54:20 2 A. I -- I don't recall that specific wording,
09:54:22 3 but that sounds like a legal approach.

09:54:27 4 Q. Today we're not going to have that kind of
09:54:30 5 opinion.

09:54:31 6 A. I'm not a lawyer. I'm not going to --
09:54:33 7 I haven't proposed my opinions in those
09:54:35 8 in -- in the framework of a -- of a -- of a
09:54:38 9 litigation -- legally-based litigation aspect.

09:54:42 10 Q. And therefore you're not going to be giving
09:54:44 11 an opinion about whether the design of the Bair Hugger
09:54:46 12 device was negligent or non-negligent.

09:54:54 13 A. Well I guess I have to understand the
09:54:56 14 parameters of the definition and what that entails.
09:55:00 15 You know, I understand that from a -- from a --

09:55:04 16 I understand at least that from a -- from a
09:55:06 17 legal position that there's -- one has to be very
09:55:10 18 careful in how one approaches the negligence and
09:55:12 19 defect in regard to how that is defined in a
09:55:16 20 particular state or particular MDL versus as FDA may
09:55:19 21 define safety and effectiveness and how that -- those
09:55:23 22 things differ.

09:55:23 23 Q. Okay. Similarly, likewise -- because you
09:55:26 24 brought up the term, it's going to be my next
09:55:29 25 question -- is about the concept of defect. And are

09:55:31 1 you going to be giving an opinion in this case that
09:55:33 2 the Bair Hugger is or is not defective?

09:55:36 3 A. I haven't rendered an opinion on that.

09:55:38 4 Q. Okay.

09:55:39 5 A. My position is, from a reg -- regulatory
09:55:42 6 perspective, were these products found substantially
09:55:45 7 equivalent or the basis for ---for those findings, so
09:55:51 8 on and so forth.

09:55:52 9 Q. Okay. We had talked a little bit earlier
09:56:00 10 about the 510(k) clearance process and about clearance
09:56:04 11 being granted when a product is found to be
09:56:06 12 substantially equivalent to a previously-legally-
09:56:09 13 marketed device. Do you remember that?

09:56:11 14 A. Yes.

09:56:11 15 Q. Okay. In terms of what "substantially
09:56:15 16 equivalent" means, you would agree that that means the
09:56:18 17 product has the same intended use and same
09:56:22 18 technological characteristics, or it may have
09:56:25 19 differences but those do not raise new questions of
09:56:28 20 safety or effectiveness.

09:56:29 21 A. Yes. That's how the statute and -- and --
09:56:32 22 is embedded in the regulations.

09:56:34 23 Q. Okay. You would also agree with me that the
09:56:36 24 510(k) process is a very liberal process in regards to
09:56:40 25 the uses of its products.

09:56:41 1 MS. EATON: Object to the form of the
09:56:43 2 question.

09:56:43 3 A. Repeat that, please.

09:56:45 4 Q. Sure. The 510(k) process is a very liberal
09:56:49 5 process in regard to the uses of products.

09:56:52 6 MS. EATON: Object to the form of the
09:56:53 7 question.

09:56:53 8 A. Well I guess it's the last part, "in the
09:56:58 9 uses of products." I think -- I guess I don't
09:56:58 10 understand your phraseology.

09:56:59 11 Q. Okay. It's your phraseology as well, not
12 that you --

09:57:00 13 Do you remember giving that testimony in
09:57:02 14 I-Flow?

09:57:02 15 A. I don't recall that, but, you know, the
09:57:06 16 context probably would make it clear to me what I was
09:57:11 17 saying or --

09:57:12 18 Q. Okay. Sure. We can do that.

09:57:15 19 THE REPORTER: Let's go off the record a
09:57:16 20 moment, please.

09:57:49 21 (Discussion off the record.)

09:57:49 22 BY MR. BANKSTON:

09:57:53 23 Q. Sir, I'm going to hand you page 130 of your
09:57:56 24 deposition in I-Flow, and I'd like to talk to you a
09:58:04 25 little bit about the question that begins on line

09:58:06 1 four, and that question reads:

09:58:09 2 "Did the -- Did I-Flow add anything to the
09:58:11 3 labeling to be more specific with regards to where it
09:58:16 4 was -- would not -- what type of surgeries it was not
09:58:18 5 to be used in?"

09:58:19 6 The answer was: "Well, then we get into the
09:58:22 7 issue of 510(k) clearances and what -- and what it all
09:58:26 8 means. The 510(k) process is a very liberal process
09:58:29 9 in regards to uses of products. It's a building-block
09:58:33 10 process where prior clearances have just as much
09:58:37 11 importance and effect as the current submission."

09:58:39 12 Do you agree with that testimony today?

09:58:40 13 A. Right. And this was in regard to
09:58:44 14 indications for use of the product. I-Flow was --

09:58:48 15 There was a particular issue about this --
09:58:52 16 this pump's usage in -- in certain clinical
09:58:56 17 conditions, and my point was very broad indications
09:59:00 18 allow very broad uses.

09:59:08 19 Q. We have some discussion in various reports
09:59:28 20 in this case about indications for use of this
09:59:28 21 product; right?

09:59:28 22 A. Right. Environments of use. Intended use
09:59:28 23 mostly.

09:59:28 24 Q. Correct. Okay. In regards to how that
09:59:28 25 process is carried out when looking at a product by

09:59:28 1 the FDA in terms of its intended uses, indications for
09:59:29 2 use, you will agree that that is a very liberal
09:59:29 3 process.

09:59:29 4 MS. EATON: Object to the form of the
09:59:30 5 question.

09:59:34 6 A. It can be liberal, it can be narrow, so --

09:59:37 7 As Congress stated and as FDA has
09:59:41 8 implemented the 510(k) process, it's not so broad as
09:59:43 9 to let everything through the door, nor should it be,
09:59:47 10 nor is it so narrow as to require everything -- or
09:59:50 11 many things to be Class III and go through PMA. So
09:59:53 12 it -- it varies depending on the product, the proposed
09:59:58 13 use of the product, the history of the products, the
10:00:01 14 current literature. So, you know, very liberal at
10:00:04 15 times, yes.

10:00:05 16 There's an evolutionary progression of
10:00:08 17 products based upon 510(k)s. In other cases FDA is
10:00:12 18 very -- more measured in regard to 510(k) clearance.

10:00:19 19 Q. So it depends on what case you're in and
10:00:21 20 what questions are being asked, what product you're
10:00:23 21 looking at, whether the 510(k) process is liberal or
10:00:25 22 not.

10:00:26 23 A. I think it -- it depends on the product,
10:00:29 24 right, yes.

10:00:31 25 Q. Your opinion, though, is that the FDA's

10:00:33 1 review of 510(k) marketing applications is rigorous.

10:00:37 2 A. Yes.

10:00:37 3 Q. Okay. You will agree with me a front-line

10:00:41 4 510(k) review approximately around the time that this

10:00:43 5 product was reviewed was done in about 20 hours

10:00:46 6 average?

10:00:47 7 MS. EATON: Object to the form of the

10:00:48 8 question.

10:00:48 9 A. No, I -- I disagree with that.

10:00:50 10 Q. You agreed with that when Mr. Lanier asked

10:00:55 11 you it last year in I-Flow; correct? Excuse me, in

10:00:57 12 DePuy.

10:00:58 13 A. That -- that's -- that's from the Supreme

10:01:00 14 Court Medtronic/Loehr again, which is old, old data. I

10:01:04 15 could talk about it for --

10:01:06 16 Let me -- let me just boil it down. That

10:01:09 17 data was based upon early-1980s 510(k) information

10:01:14 18 when Class I devices were reviewed as well as Class II

10:01:18 19 devices. After that point in time when -- when the

10:01:21 20 Supreme Court evaluated that data, FDA exempted all

10:01:27 21 the Class I devices, so they were off the table for

10:01:30 22 510(k)s, and FDA concentrated on Class II. The actual

10:01:34 23 review time since early '90s up until current has been

10:01:38 24 constantly moving upward, so 20 hours per 510(k) is an

10:01:43 25 old, old number.

10:01:43 1 Q. Your testimony is that since 1985 the
10:01:48 2 efficiency -- for lack of a better word -- of the
10:01:50 3 device office in approving medical devices through
10:01:53 4 510(k), the -- their ability to do that has
10:01:57 5 consistently improved since 1985.

10:01:59 6 MS. EATON: Object to the form of the
10:02:00 7 question.

10:02:01 8 A. Coupled with the complex -- increased
10:02:04 9 complexity of submissions, it has had to do so. But
10:02:07 10 the fact of the matter is the data show -- FDA's own
10:02:10 11 data show a constant increase in the review time --
10:02:13 12 average review time for 510(k)s over -- over time.

10:02:15 13 Q. A constant increase or decrease?

10:02:18 14 A. Increase.

10:02:18 15 Q. In review time?

10:02:19 16 A. Yes.

10:02:20 17 Q. It takes longer to review 510(k)s in 2003
10:02:23 18 than it did in 1985.

10:02:24 19 A. That's correct.

10:02:25 20 Q. Okay. You're familiar that right about the
10:02:32 21 time before you left in 2001, around the 2010
10:02:37 22 timeframe with your new FDA commissioner, an
10:02:41 23 investigation and a committee report was begun and put
10:02:44 24 together by what was then known as the Institute of
10:02:47 25 Medicine reviewing the 510(k) process.

10:02:50 1 A. Right, yes. The IOM, yes.

10:02:52 2 Q. And then as soon as IO --

10:02:55 3 Like when the IOM came out is roughly

10:02:57 4 concurrent with when you left the agency.

10:03:00 5 A. When the report came out, yes.

10:03:01 6 Q. Correct. That report --

10:03:02 7 MS. EATON: Can I just clarify? You said

10:03:05 8 2001, and I think you meant 2011.

10:03:08 9 MR. BANKSTON: That is true.

10:03:09 10 THE WITNESS: Yeah. I let that go by.

10:03:09 11 MS. EATON: I just want that to be clear on

10:03:11 12 the record.

10:03:11 13 Q. Yeah. You left the agency in 2011.

10:03:14 14 A. '11, yes.

10:03:14 15 Q. That's when the IOM report was published.

10:03:17 16 A. It was thereabouts, yes.

10:03:19 17 Q. Okay. That IOM report states/finds that the

10:03:21 18 510(k) process was not designed to determine whether a

10:03:23 19 new device provides a reasonable assurance of safety.

10:03:29 20 A. Yeah. The -- the IOM --

10:03:32 21 There's only two real conclusions in the IOM

10:03:36 22 report, and one of them is the 510(k) process was not

10:03:39 23 designed to evaluate safety and effectiveness in

10:03:44 24 certain cases, but the fact of the matter is, as FDA

10:03:49 25 has implemented the process, it certainly had to

10:03:52 1 consider safety and effectiveness aspects in its
10:03:55 2 review of 510(k)s.

10:03:56 3 Q. Okay. There are two relevant opinions in
10:03:59 4 this report?

10:03:59 5 A. Well there's two -- two -- two general
10:04:02 6 opinions, and then there's other findings in the
10:04:04 7 report.

10:04:04 8 Q. Okay. Let's talk about some of those
10:04:07 9 findings. You understand that one of the things the
10:04:10 10 IOM found was that congressional appropriations for
10:04:14 11 the operation of 510(k) clearance have been unstable
10:04:18 12 and frequently inadequate throughout its lifespan.

10:04:22 13 A. Yes, I agree.

10:04:24 14 Q. Now when you were an FDA director you were
10:04:28 15 in the Center for Devices and Radiological Health;
10:04:31 16 correct?

10:04:31 17 A. Correct.

10:04:31 18 Q. Okay. Your division by far received the
10:04:35 19 most 510(k)s of any division within the Office of
10:04:38 20 Device Evaluation.

10:04:40 21 A. I believe so.

10:04:41 22 Q. Okay. Now you --

10:04:42 23 When that was going on, you had a few staff
10:04:46 24 who could review general hospital devices, and you
10:04:48 25 reviewed all the devices and were responsible for all

10:04:51 1 the devices in the division; correct?

10:04:54 2 A. Well that's a --

10:04:55 3 You made multiple statements there.

10:05:00 4 Q. Uh-huh.

10:05:00 5 A. Yes, I was the director of a division that
10:05:00 6 handled several types of devices. We had a staff
10:05:03 7 of -- well it varied over time -- 30 to 50 individuals
10:05:10 8 I would say, and we reviewed a number of 510(k)s.

10:05:13 9 Q. And you reviewed --

10:05:15 10 MS. EATON: I just want to go back and
10:05:16 11 object to the form of that question. Thank you.

10:05:19 12 Q. You reviewed all the devices.

10:05:19 13 A. I reviewed all the --

10:05:21 14 Q. Correct?

10:05:22 15 A. Well, ultimately the division director signs
10:05:25 16 off on the 510(k)s.

10:05:27 17 Q. Correct. You were --

10:05:27 18 A. But then there's a process, yes.

10:05:28 19 Q. You were responsible for all the devices in
10:05:30 20 that division.

10:05:31 21 A. Yes, I would say so.

10:05:32 22 Q. Okay. During that time period you would see
10:05:37 23 on a given date potentially dozens and dozens of
10:05:40 24 510(k)s.

10:05:42 25 A. Not on average, but, you know, there were

10:05:45 1 days where there were more and days where there were a
10:05:48 2 lot fewer, so it depends.

10:05:50 3 Q. You have testified previously that on a
10:05:52 4 given date you could see dozens and dozens of 510(k)
10:05:55 5 clearances.

10:05:55 6 A. On a given date, yes.

10:05:57 7 Q. Uh-huh. You had to rely on your front-line
10:06:02 8 reviewers. You would agree with me?

10:06:05 9 A. Yes. And others that -- individuals that
10:06:08 10 were bought -- brought to bear in evaluating 510(k)s.
10:06:10 11 For example, we enlisted the assistance of the Science
10:06:16 12 Division to review 510(k)s, we enlisted the assistance
10:06:20 13 of advisory committee members to review 510(k)s, and
10:06:24 14 others. So I had a core of reviewers, the division,
10:06:27 15 but there were other reviewers that assisted.

10:06:30 16 Q. Right. What you saw at the end of the
10:06:33 17 process from your perspective running that division,
10:06:38 18 being responsible for all these devices, what you saw
10:06:39 19 was a stack of blue folders with letters with a space
10:06:42 20 for your signature; right? You -- you didn't --

10:06:45 21 You had no time to review those 510(k)s.

10:06:48 22 MS. EATON: Object to the form of the
10:06:49 23 question.

10:06:49 24 A. I did review several of them. It depended
10:06:51 25 on the 510(k). So if they were, I'll call them,

10:06:56 1 routine documents, because you would receive
10:07:02 2 submissions for -- for devices that -- that were very
10:07:06 3 routine sorts of changes or new devices, and others
10:07:10 4 that were much more complex. You had to take some
10:07:13 5 time on those 510(k)s.

10:07:14 6 Q. Well I want to make sure I understand you.

10:07:18 7 You're saying -- I mean --

10:07:18 8 Well let me put it this way: You're saying
10:07:20 9 you would not say you had no time to review those
10:07:22 10 510(k)s.

10:07:22 11 A. I -- I --

10:07:23 12 Well it's not the same thing. I decided
10:07:25 13 that, based on the product, based on the reviewer and
10:07:29 14 the branch chief's evaluation, I could rely upon those
10:07:34 15 decisions. In other cases I found it necessary to
10:07:37 16 evaluate the 510(k) myself as well.

10:07:39 17 Q. Right. But what I'm saying is when you'd
10:07:40 18 get a stack of blue folders on your desk, you had no
10:07:44 19 time to review those, you're just signing a letter.
10:07:47 20 There's no way you can review every device that passes
10:07:50 21 through your office.

10:07:50 22 A. Nor did I find it necessary to do so.

10:07:52 23 Q. Okay. And there are times when your lower-
10:07:56 24 level employees, these people you're relying on to do
10:07:59 25 the reviews, there are times when they did not make

10:08:01 1 the appropriate recommendations to you; correct?

10:08:03 2 A. Well I think it's a very rare instance.

10:08:15 3 I've only uncovered, I think, one circumstance when I

10:08:19 4 think, given the review criteria at the time, given

10:08:21 5 the proc -- procedures at the time, that -- that there

10:08:25 6 were -- there were problems with any of the 510(k)

10:08:27 7 clearances.

10:08:28 8 Q. What one specific instance is that?

10:08:30 9 A. Well as I mentioned, I think, I -- I perused

10:08:34 10 litigation-produced documents in I-Flow and identified

10:08:38 11 some new information. I thought, you know, if we had

10:08:40 12 brought that to bear, maybe we could have made a

10:08:43 13 different decision. But, you know, that's based on

10:08:45 14 new information.

10:08:46 15 Q. Okay.

10:09:05 16 (Discussion off the stenographic record.)

10:09:05 17 (Ulatowski Exhibit 1 was marked for

10:09:08 18 identification.)

10:09:08 19 BY MR. BANKSTON:

10:09:09 20 Q. Mr. Ulatowski, I've put in front of you the

10:09:12 21 IOM report so we can kind of follow along with each

10:09:15 22 other, --

10:09:15 23 A. Uh-huh.

10:09:15 24 Q. -- and I was wondering if you could flip to

10:09:17 25 65 for me.

10:09:18 1 A. Sure.

10:09:20 2 Q. Okay. Now I want to --

10:09:21 3 As you're doing that, the division that you
10:09:26 4 were in charge of is the Center for Device and
10:09:30 5 Radiological Health.

10:09:32 6 MS. EATON: Object to the form of the
10:09:33 7 question.

10:09:34 8 A. No.

10:09:34 9 Q. Okay. What association did you have with
10:09:36 10 the CDRH?

10:09:37 11 A. I was --

10:09:40 12 In my final position I was the director of
10:09:44 13 the Office of Compliance within the Center for Devices
10:09:47 14 and Radiological Health.

10:09:48 15 Q. Okay. So you were a director in CDRH at the
10:09:54 16 time you left the agency.

10:09:54 17 A. An office director, yes.

10:09:54 18 Q. An office director. Okay.

10:09:55 19 You understand that around the time that you
10:09:59 20 were leaving the FDA, that there had been an FDA
10:10:02 21 working group formed to examine the CDRH and what it
10:10:08 22 was doing in approving devices.

10:10:10 23 A. Yes.

10:10:10 24 Q. Okay. That was running concurrently,
10:10:12 25 basically, with IOM's investigation of 510(k)s.

10:10:16 1 A. Yes.

10:10:16 2 Q. Okay. You'll agree -- and I have some
10:10:19 3 language there I believe you'll see there on page
10:10:21 4 65 -- and you'll agree that the working group found
10:10:26 5 that the Center for Devices and Radiological Health
10:10:29 6 does not have an adequate mechanism to regularly
10:10:32 7 assess the quality, the consistency, and the
10:10:35 8 effectiveness of the 510(k) program. I'm assuming you
10:10:39 9 were made aware of that.

10:10:40 10 A. Yeah. Let me just read it. I -- I recall
10:10:42 11 it.

10:10:50 12 Yes, I understand this. I -- I think it's
10:10:53 13 not quite accurate in that CDRH actually had gone
10:11:01 14 through --

10:11:01 15 If you were there long enough -- you know,
10:11:04 16 37 years -- you would have been aware, and these -- I
10:11:09 17 don't think these people have awareness of it, but FDA
10:11:12 18 had -- had been through previous cycles of analysis of
10:11:16 19 the 510(k) program, had undergone a -- an intensive
10:11:22 20 evaluation of the 510(k) program and consistency in
10:11:26 21 the 510(k) program and retrospective analysis of prior
10:11:31 22 510(k) decisions, one of them is called the Temple
10:11:34 23 Report, and I think what this group was saying, we
10:11:38 24 need to build in that sort of review process more
10:11:42 25 frequently and more systematically than what we've

10:11:47 1 done in the past. But FDA had done so in the past,
10:11:49 2 looked at that -- these very same topics.

10:11:52 3 MR. BANKSTON: I'll object as
10:11:53 4 non-responsive.

10:11:53 5 Q. I asked if you were aware of the findings.

6 A. Yes.

10:11:55 7 Q. Are you aware of the findings?

10:11:57 8 A. Yes.

10:11:57 9 Q. Okay. You were also aware that the IOM
10:12:00 10 reviewed what the working group did and said we agree
10:12:02 11 with the working group that there's not an adequate
10:12:05 12 mechanism to regularly assess the quality,
10:12:08 13 consistency, or effectiveness of the 510(k) program.

10:12:13 14 A. Well I don't -- I don't recall if the IOM
10:12:15 15 said we agree. I know the IOM took up some of the
10:12:21 16 working group's findings and embedded them in the
10:12:23 17 report -- in their report.

10:12:24 18 Q. Can you look at page 65, at the top of that
10:12:29 19 page, and tell me if that helps you understand whether
10:12:30 20 they agreed with the 510(k) working group.

10:12:32 21 A. Okay. They do say agree, --

10:12:34 22 Q. Okay.

10:12:34 23 A. -- so I stand corrected. But my -- my point
10:12:38 24 is they -- they lifted the working group's report into
10:12:40 25 their report without a lot of foundation. But it is

10:12:44 1 what it is.

10:12:44 2 Q. So you're saying you're critical of what --
10:12:46 3 the job the IOM did.

10:12:48 4 A. Well I can take issue in a number of things.
10:12:50 5 For example, the -- the -- the IOM did not evaluate in
10:12:56 6 any significant manner any 510(k)s, so it's all kind
10:13:01 7 of theoretical based upon legal foundation,
10:13:06 8 Medtronic/Lohr and -- and whatnot, but nobody went in
10:13:09 9 there and started reviewing 510(k)s to any extent to
10:13:12 10 say -- to see, well, this is a 510(K), let me see
10:13:14 11 what -- what FDA did with this particular 510(k) or
10:13:19 12 that particular 510(k).

10:13:20 13 Q. Okay.

10:13:21 14 A. So it's all kind of theoretical on the part
15 of the IOM.

16 Q. So your testimony -- oh, excuse me.

17 Your testimony is that during the IOM
10:13:29 18 investigation, nobody did an audit of any 510(k)
19 approvals to see whether they were appropriate or not
10:13:34 20 or made any efforts to understand that process of
10:13:34 21 approving 510(k)s for specific devices.

10:13:36 22 A. Yeah. They didn't have time. They -- they
10:13:38 23 didn't do that sort of analysis.

10:13:40 24 Q. Okay. You're familiar with the publication
10:13:41 25 called The FDA Daily News?

10:13:45 1 A. I think so.

10:13:47 2 Q. You've been quoted in that publication on
10:13:50 3 several occasions.

10:13:50 4 A. Probably.

10:13:51 5 Q. Do you remember telling that publication and
10:13:54 6 it having been published that you had said that over
10:13:57 7 your time at -- in Device Evaluation, that the FDA's
10:14:04 8 device experience in the field had shrunk?

10:14:07 9 A. Yes, and that -- and that's a fact. In
10:14:11 10 the -- in the field, --

10:14:12 11 Q. Uh-huh.

10:14:13 12 A. -- not in Device Evaluation.

10:14:15 13 Q. In fact, the FDA has made efforts within the
10:14:18 14 past 10 to 15 years to recruit support from the
10:14:23 15 private sector in terms of device experience and
10:14:27 16 expertise.

10:14:27 17 A. Right, third -- third-party reviews for
10:14:30 18 example.

10:14:30 19 Q. Yeah. And -- and there are more private-
10:14:32 20 sector consultants who are brought in to address
10:14:35 21 various issues; correct?

10:14:36 22 A. Well they're all vetted in regard to their
10:14:40 23 conflicts and -- and carefully monitored, so there's a
10:14:45 24 process there. So it's not -- it's not a free-for-
10:14:48 25 all. It's --

10:14:48 1 Q. Sure. I mean the FDA is rigorous about
10:14:50 2 this. It values that support.

10:14:52 3 A. Correct.

10:14:52 4 Q. And one of those people would be Dr. Yadin
10:14:56 5 David.

10:14:57 6 A. I comment on my understanding of
10:15:00 7 his, based on his CV that he produced and my fading
10:15:05 8 knowledge of my interaction with him, what his
10:15:08 9 experience was.

10:15:08 10 Q. Uh-huh. He was a private-sector consultant
10:15:10 11 that was engaged by the FDA.

10:15:13 12 MS. EATON: Object to the form of the
10:15:15 13 question.

10:15:15 14 A. Well he attests to the fact that he's on the
10:15:20 15 GMP committee. I don't think he attests to anything
10:15:22 16 more.

10:15:22 17 Q. He's on several committees according to his
10:15:25 18 CV; isn't he?

10:15:26 19 A. Not FDA committees --

10:15:27 20 Q. Okay.

10:15:28 21 A. -- is my understanding from his CV.

10:15:32 22 Q. Okay. You'll agree with me that it's the
10:15:34 23 manufacturer, not the FDA, who is primarily
10:15:37 24 responsible for the assurance of safety of medical
10:15:39 25 devices.

10:15:45 1 A. Yes. The regulations are geared to the fact
10:15:47 2 that the manufacturer must follow regulations in order
10:15:52 3 to design and manufacture and monitor the devices,
10:15:56 4 with the surveillance and oversight of FDA.

10:15:58 5 Q. Right. The FDA can't monitor each and every
10:16:01 6 manufacturer and the marketing of each and every
10:16:04 7 product; can it?

10:16:04 8 A. No. That's why FDA prioritizes its
10:16:07 9 monitoring and its evaluation of devices.

10:16:20 10 Q. One of the opinions you give in your report
10:16:24 11 is that the FDA must consider issues of safety and
10:16:26 12 effectiveness when comparing any differences in
10:16:31 13 indications for use in claims. You'd agree with that?

10:16:33 14 A. Correct.

10:16:33 15 Q. Okay. And -- and I think, as we saw from
10:16:36 16 your I-Flow testimony, you'll agree that prior
10:16:38 17 clearances have just as much importance and effect as
10:16:41 18 current clearances.

10:16:42 19 MS. EATON: Object to the form of the
10:16:44 20 question.

10:16:44 21 A. Yes. They have an impact on assessing
10:16:47 22 indications and intended use.

10:16:48 23 Q. The prior clearances have just as much
10:16:54 24 importance as the current submission.

10:16:56 25 MS. EATON: Object to the form of the

10:16:56 1 question.

10:16:57 2 A. Well yes, because of the appliance of
10:16:59 3 current usage of the current product being submitted.

10:17:03 4 Q. Now when the Bair Hugger was first legally
10:17:05 5 cleared, it was because the manufacturer assured the
10:17:08 6 FDA that it was substantially equivalent to a device
10:17:11 7 that had been legally marketed before; correct?

10:17:13 8 A. Yes.

10:17:14 9 Q. Okay. What device was that?

10:17:15 10 A. Are we talking about Sweetland early on?

10:17:18 11 Q. Is that the first one you know about?

10:17:20 12 A. Well that's -- that's in the 200 series.
10:17:25 13 Then the 500 series and 700 series came along. But I
10:17:29 14 think that's what the focus was of Dr. David.

10:17:34 15 Q. Sure. Let's -- and let's go through --
10:17:34 16 Let's do the history, because as we say,
10:17:37 17 it's -- each submission builds on the last; right?

10:17:39 18 MS. EATON: Object to the form of the
10:17:40 19 question.

10:17:40 20 A. Right. There's a -- there's a --
10:17:42 21 equivalence has a --

10:17:44 22 There's an evolutionary comparison with
10:17:46 23 prior devices. The manufacturer identifies the
10:17:49 24 particular predicate that -- upon which they want to
10:17:53 25 compare the new product to, but behind that are -- is

10:17:57 1 a history of other devices that -- that may be
10:17:59 2 relevant or may not be relevant, but -- but -- and so
10:18:02 3 it's a -- it's on a case-by-case basis.

10:18:06 4 Q. Well the prior clearances have just as much
10:18:09 5 importance as the current submission; right? Because
10:18:09 6 they're relevant.

10:18:10 7 MS. EATON: Object to the form of the
10:18:11 8 question.

10:18:11 9 A. Well they're relevant, but as far as their
10:18:13 10 application to a particular new device, there may be a
10:18:16 11 break in the chain of equivalence where they're not as
10:18:19 12 relevant as before. But they're all important. Every
10:18:21 13 510(k) is important. Every 510(k) in the history has
10:18:26 14 some contribution to the new device, some aspect.

10:18:30 15 Q. I want to ask you about that term you used,
10:18:33 16 a break in the chain of substantial equivalence.

10:18:37 17 A. Correct.

10:18:38 18 Q. Does that exist in this case?

10:18:40 19 A. No. I think -- I think there's a --

10:18:42 20 Not in the form that I've described in other
10:18:44 21 cases.

10:18:44 22 Q. All right. Well then what I want to do is
10:18:47 23 go through the history of the products that stack on
10:18:49 24 each other. All right?

10:18:51 25 A. Sure.

10:18:51 1 Q. So the first product that we know about is
10:18:52 2 the Bair Hugger 200 series; correct?

10:18:54 3 A. That's the first one that I think I -- Dr.
10:18:58 4 David references, I think, in my listing of products.

10:19:01 5 Q. Yeah. You didn't find anything earlier than
10:19:04 6 that; right?

10:19:04 7 A. No.

8 Q. Okay.

10:19:05 9 A. No.

10:19:07 10 Q. So that product --

10:19:07 11 A. Not based upon my search terms.

10:19:08 12 Q. That product has a predicate.

10:19:11 13 A. Right.

10:19:11 14 Q. And that product is the Sweetland Bed Warmer
10:19:14 15 and Cast Dryer; correct?

10:19:16 16 A. Correct.

10:19:18 17 Q. And can you describe to me what that product
10:19:19 18 is, what it does?

10:19:20 19 A. That -- that was a product used, I think,
10:19:23 20 for hospital use for warming, but it was -- it was --

10:19:27 21 I don't recall the specifics. I'd have to
10:19:29 22 look at my report.

10:19:30 23 Q. Okay. Do you know when that product was
10:19:32 24 made?

10:19:33 25 A. That was probably back in the '80s, nine --

10:19:37 1 early '90s.

10:19:38 2 Q. Would it surprise you that the Sweetland Bed
10:19:41 3 Warmer was designed and manufactured in 1932?

10:19:44 4 A. Yeah. That's why I'd have to look at my
10:19:47 5 report to see what I referenced.

10:19:48 6 Q. Okay.

10:19:49 7 A. But I wouldn't be surprised.

10:19:51 8 Q. Wouldn't be surprised if the Bair Hugger 200
10:19:53 9 series is held to be substantially equivalent to a
10:19:55 10 cast dryer in the 1930s.

10:19:58 11 A. Not particularly. I think when -- when
10:20:00 12 510(k)s are being submitted, when you're evaluating
10:20:05 13 predicates pre-'76, 1976 predicates are -- are
10:20:10 14 eligible as predicates based on technology and -- and
10:20:15 15 whatnot, so --

10:20:16 16 And that's the way the law is structured.
10:20:18 17 So yes, it's a -- it's a legitimate predicate.
10:20:22 18 Potential predicate, let me put it that way.

10:20:24 19 Q. Okay. So that Bair Hugger device was
10:20:28 20 submitted, the Bair Hugger 200 series, and it had the
10:20:32 21 predicate of the Sweetland Bed Warmer and Cast Dryer,
10:20:36 22 and in doing so it had to represent that that device
10:20:37 23 either had the same IFUs, indications for use, and
10:20:41 24 technological characteristics, or it had differences,
10:20:44 25 but those differences didn't affect health and safety

10:20:46 1 and effectiveness; is that correct?

10:20:48 2 MS. EATON: Object to the form of the
10:20:49 3 question.

10:20:50 4 A. Not --

10:20:52 5 That's not precise.

10:20:52 6 Q. Okay.

10:20:52 7 A. First of all, the -- that the new device to
10:20:56 8 which comparison was made to the predicate had the
10:21:01 9 same intended use as the predicate.

10:21:03 10 Q. Okay.

10:21:04 11 A. And intended use in this case with these
10:21:07 12 types of devices are what's the functional purpose of
10:21:11 13 the product.

10:21:11 14 Q. Can you help me understand. Is there a --
10:21:14 15 is there a distinction between indications for use and
10:21:17 16 intended use?

10:21:17 17 A. Yes, there is.

10:21:18 18 Q. Okay.

10:21:18 19 A. Yeah.

10:21:19 20 Q. So from what I understand, indications for
10:21:21 21 use is -- is how the company communicates through its
10:21:25 22 labeling and otherwise the purposes of the product; is
10:21:29 23 that fair?

10:21:30 24 How would you define "indications for use?"

10:21:33 25 A. Well indications for use is -- are the --

10:21:38 1 the diseases, the conditions, the patient populations
10:21:43 2 for use of the product in a similar manner that
10:21:46 3 drugs -- drug indications are --

10:21:47 4 Q. Okay.

10:21:48 5 A. -- identified in the labeling. Intended use
10:21:50 6 is a functional purpose of a product, generally, which
10:21:54 7 may be determined through indications for use through
10:21:57 8 other claims in the submission.

10:21:58 9 Q. Yeah. Okay.

10:21:59 10 A. So the intended use of the Bair Hugger has
10:22:04 11 always, as I said in my report, has always been the
10:22:07 12 heating of patients, the intended use has never
10:22:12 13 changed, and -- and so inasmuch as the Sweetland was
10:22:15 14 used for heating patients, had the same intended use.

10:22:18 15 Q. What are the indications for use for the
10:22:19 16 Bair Hugger?

10:22:22 17 MS. EATON: Object to the form of the
10:22:23 18 question.

10:22:24 19 A. I don't --

10:22:24 20 Well hypothermia is a -- is a clinical
10:22:26 21 application, so it's an indication of sorts.

10:22:28 22 Q. Okay. So you would agree with me, though,
10:22:34 23 that when the first Bair Hugger, the Bair Hugger 200
10:22:36 24 series, was introduced, it was represented as being
10:22:41 25 substantially equivalent as the Sweet -- Sweetland Bed

10:22:45 1 Warmer and Cast Dryer.

10:22:47 2 A. Correct.

10:22:47 3 Q. Okay.

10:22:47 4 A. And also we're aware that FDA had -- had
10:22:50 5 classified that group of products, it's a Class II, so
10:22:55 6 FDA was recognizing through that classification that
10:22:58 7 there were predicate devices in the marketplace, at
10:23:02 8 least at one point in time prior to '76, that could be
10:23:05 9 used as predicate.

10:23:06 10 Q. Okay. In other words, Arizant assured the
10:23:12 11 FDA that either those two pro -- products had the same
10:23:17 12 intended uses or maybe different intended uses, but
10:23:21 13 those differences did not affect safety or
10:23:24 14 effectiveness.

10:23:25 15 MS. EATON: Object to the form of the
10:23:26 16 question.

10:23:26 17 A. Right. That's part of the intended use
10:23:30 18 evaluation and that's one point -- the first point
10:23:32 19 where safety and effectiveness comes into play.

10:23:34 20 Q. Okay.

10:23:35 21 A. Or this term safety and eff -- these terms,
10:23:39 22 safety and effectiveness. Well here we are. So FDA
10:23:40 23 will evaluate the labeling for the Sweetwater --
10:23:44 24 Sweet -- yeah, Sweetland device and -- if the labeling
10:23:50 25 is available, it's al -- it's sometimes a challenge to

10:23:55 1 get predicate labeling, and the new product labeling
10:23:57 2 to kind of match things up and to identify any
10:24:00 3 differences. Plus, FDA relies upon other information
10:24:04 4 it may have -- it may bring to bear, other
10:24:06 5 submissions, literature, other marketing information
10:24:09 6 it may have at hand, to try and analyze the intended
10:24:12 7 use, the similarity of intended use.

10:24:14 8 MR. BANKSTON: Okay. Object as
10:24:15 9 non-responsive.

10:24:17 10 Q. When -- when the Bair Hugger 200 was first
10:24:23 11 submitted to the FDA, there was no indication that
10:24:29 12 that product may ever be inside of an operating room.
10:24:32 13 Would you agree with me that?

10:24:35 14 A. Yeah. Looking at the 200, I didn't see
10:24:38 15 reference to OR use.

10:24:40 16 Q. In fact, the company knew that it wasn't
10:24:43 17 going to sell it into ORs. You understand that?

10:24:46 18 MS. EATON: Object to the form of the
10:24:48 19 question.

10:24:48 20 A. I don't know that specifically, but I
10:24:50 21 wouldn't be surprised.

10:24:50 22 Q. Do you remember in the depositions that you
10:24:52 23 reviewed seeing about warnings on the 200 for "Not for
10:24:58 24 use in ORs?" Do you remember anything like that?

10:25:01 25 A. I recall warnings, yes, in the 200.

10:25:03 1 Q. Okay. Now the third product in this series
10:25:08 2 of products, major iterations of this product, do you
10:25:11 3 understand that there was then a 500 series of Bair
10:25:14 4 Hugger?

10:25:14 5 A. Yes.

10:25:14 6 Q. Okay. Now were there any differences in
10:25:18 7 either the IFU statement, the indications for use, or
10:25:21 8 the intended uses between the 200 and the 500 series?

10:25:25 9 A. Well the intended use had not changed. The
10:25:28 10 intended use was still fundamentally the functional
10:25:33 11 use of warming patients.

10:25:35 12 Q. Okay.

10:25:36 13 A. So the intended use had not changed.

10:25:38 14 Q. What about the indications for use?

10:25:39 15 A. I think indications evolved with the 500
10:25:44 16 into the 505 into OR use.

10:25:46 17 Q. Okay. So in other words, you're telling me
10:25:50 18 that between the 200 and the 500, the company let the
10:25:56 19 FDA know that with the 500 there would be an expansion
10:26:00 20 of its indications for use into operating rooms.

10:26:04 21 A. I don't think the 50 -- 500, as I recall --
10:26:08 22 and I may be incorrect here -- discussed OR use. The
10:26:12 23 505 certainly did; that was -- that was in numerous
10:26:17 24 spots where OR use was indicated. And there was a
10:26:19 25 paper also included that referred to OR use. So, you

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10:26:24 1 know, FDA was certainly made aware at that point in
10:26:27 2 time with the 505.

10:26:29 3 As far as the 500, I'm -- I'm recollecting
10:26:32 4 the data submitted and I'm not sure if there was OR
10:26:37 5 references in there as I recall.

10:26:38 6 Q. Okay. What about the 500 OR, do you know
10:26:41 7 anything about that product?

10:26:42 8 A. Yeah. Variation of the 500 probably, yes.

10:26:47 9 Q. Okay. When the FDA became aware that the
10:26:49 10 IFUs were being expanded to include OR usage, part of
10:26:55 11 the job then of the FDA would be to determine if that
10:27:00 12 expansion of IFUs presented any new questions of
10:27:04 13 safety.

10:27:04 14 MS. EATON: Object --

10:27:05 15 A. Right.

10:27:05 16 MS. EATON: -- to the form of the question.

10:27:06 17 A. Yes. That would be an element for FDA to
10:27:09 18 consider. And we know that in the 505 they actually
10:27:12 19 considered the flip side, which was home use, as being
10:27:15 20 potentially significant. So yes, FDA was analyzing
10:27:20 21 the -- the -- the -- the possibilities for use of the
10:27:24 22 product.

10:27:24 23 Q. Okay. What did the FDA do to determine that
10:27:29 24 the Bair Hugger's expansion of use into the OR did not
10:27:33 25 pose any new questions of safety?

10:27:37 1 A. Well we don't have available to us the
10:27:40 2 reviews by FDA, so we don't -- we cannot benefit from
10:27:46 3 that, but as a -- as a matter of policy and procedure,
10:27:49 4 FDA would be required to evaluate that, bring to -- to
10:27:53 5 bring to bear not only what's been submitted but also
10:27:56 6 any other information it may bring to bear in its
10:28:00 7 knowledge of patient warming devices being used in the
10:28:03 8 OR. So -- so FDA can bring to bear, as I did numerous
10:28:08 9 times over many years and as I trained people to do,
10:28:11 10 other submissions, literature, expert opinion of -- of
10:28:16 11 individuals on staff or advisory committee members.
10:28:19 12 So it's -- it's a very -- it's a more comprehensive
10:28:23 13 input source than just a submission.

10:28:25 14 Q. I -- I'm guessing from your comments that
10:28:28 15 it -- it would be difficult for you to talk about what
10:28:32 16 happened in terms of the 500 series in terms of its
10:28:35 17 510(k) clearance process because, according to you, we
10:28:38 18 don't have the decision-making documentation produced
10:28:42 19 in this case or available for your review for you to
10:28:46 20 be able to discuss those matters.

10:28:47 21 MS. EATON: Object to the form of the
10:28:48 22 question.

10:28:48 23 A. Well I can't discuss the reviews without
10:28:50 24 having them, and having them would shed more light on
10:28:54 25 FDA's foundation for their finding of substantial

10:28:57 1 equivalence, but in the absence of that I certainly
10:29:00 2 understand the review process and what's brought to
10:29:03 3 bear.

10:29:03 4 Q. Let me -- let me back up a little bit to --

10:29:06 5 MR. BANKSTON: In fact, I can just give you
10:29:07 6 a copy of this really quick. Actually, let's mark
10:29:10 7 that as an exhibit. And I have a copy for you.

10:29:20 8 (Ulatowski Exhibit 2 was marked for
10:29:21 9 identification.)

10:29:21 10 BY MR. BANKSTON:

10:29:28 11 Q. Mr. Ulatowski, I handed you what's been
10:29:30 12 marked as Ulatowski Exhibit 2. It is an attachment to
10:29:34 13 your report; correct?

10:29:35 14 A. Yes.

10:29:35 15 Q. Okay. This is a list of materials that you
10:29:37 16 reviewed in coming to your opinions in this case.

10:29:40 17 A. Yes.

10:29:40 18 Q. Okay. These materials, were these things
10:29:44 19 that you actually went out and located yourself, or
10:29:49 20 were they things that were provided to you?

10:29:51 21 A. Some things I did, some things that were
10:29:55 22 produced in -- in the litigation.

10:29:55 23 Q. Okay. One of the things that you'll see in
10:29:57 24 this list is a long list of Bates-numbered documents;
10:30:01 25 correct?

10:30:01 1 A. Yes.

10:30:01 2 Q. Okay. I believe there's, I mean, dozens of
10:30:04 3 pages --

10:30:04 4 A. Yes.

10:30:04 5 Q. -- of documents that you have seen. And
10:30:07 6 when I say "dozens of pages," I mean dozens of pages
10:30:10 7 on that list; right?

10:30:11 8 A. Yes.

10:30:11 9 Q. In other words, hundreds if not thousands of
10:30:14 10 pages of documents you've reviewed.

10:30:16 11 A. A lot.

10:30:18 12 MS. EATON: Let me just object to the form
10:30:20 13 of the question about the --

10:30:20 14 MR. BANKSTON: Yeah. Do you want to count
10:30:22 15 them or --

10:30:22 16 MS. EATON: Yeah. It's like six. I mean
17 I --

10:30:22 18 It's a lot of documents, but it's six pages.

10:30:25 19 MR. BANKSTON: Oh, okay. Maybe we're
10:30:26 20 talking about the study stuff.

10:30:27 21 Q. Let's --

10:30:30 22 With respect to how many pages are in your
10:30:32 23 actual exhibit there, you will agree with me there are
10:30:34 24 hundreds if not thousands of pages you've reviewed in
10:30:37 25 terms of Bates-labeled documents.

10:30:38 1 A. Right. And, you know, I was engaged in
10:30:41 2 prior litigation, so that's additive to this
10:30:45 3 particular MDL work.

10:30:46 4 Q. You mean that one of the cases that's
10:30:48 5 currently before this court has been pending for some
10:30:51 6 time.

10:30:51 7 A. A couple of them, yes.

10:30:55 8 Q. Right. And you've done work in those cases.

10:30:55 9 A. Right. So, you know, time added there
10:30:57 10 because a lot of documents are -- are the same, just
10:31:00 11 with different Bates numbers.

10:31:03 12 Q. In other words, some of these documents were
10:31:13 13 produced a couple years ago, some of them were
10:31:16 14 produced more recently.

10:31:16 15 A. Correct. In Walton and Johnson, for
10:31:19 16 example.

10:31:19 17 Q. Correct.

18 A. Yes.

10:31:20 19 Q. So some of your review of documents occurred
10:31:22 20 a couple years ago, some of it occurred recently; is
10:31:25 21 that right?

10:31:25 22 A. Right. I looked at new information, but
10:31:28 23 already at hand, all that information I had received
10:31:32 24 in Walton and Johnson, which was essentially the same
10:31:36 25 documentation in many respects.

10:31:38 1 Q. Okay.

10:31:38 2 A. Not all respects, but many respects.

10:31:41 3 Q. Now these documents that we're talking about
10:31:42 4 here, the ones that have 3M at the front of them or
10:31:46 5 3MBH at the front of them, those are documents that
10:31:50 6 were given to you; right?

10:31:50 7 A. Or I asked for, yes.

10:31:52 8 Q. All right. So you might have requested
10:31:53 9 certain types of documents and this is what was
10:31:56 10 provided to you.

10:31:56 11 A. Yes.

10:31:56 12 Q. Okay. One of the things you might want to
10:31:58 13 see is 510(k) documents; right?

10:32:00 14 A. Yes.

10:32:01 15 Q. Okay. So one of the things listed on your
10:32:03 16 list here is 510(k) documents.

10:32:05 17 A. Yes.

10:32:07 18 Q. And other things might be additional
10:32:08 19 regulatory materials. There's a large category of
10:32:10 20 documents that fit that on your list; right?

10:32:13 21 A. Yes.

10:32:13 22 Q. Okay. These sorts of things that you've
10:32:15 23 relied on to give your opinions about the 510(k)
10:32:17 24 process in this case.

10:32:18 25 A. Yes.

10:32:19 1 Q. Included within that scope of documents you
10:32:23 2 do not -- you were not provided the decision-making
10:32:26 3 documents for the 510(k) approval process for the
10:32:29 4 series 500 Bair Hugger.

10:32:32 5 A. No. I don't have those. I have no
10:32:36 6 knowledge if they exist. But those would be obtained
10:32:39 7 through Freedom of Information requests.

10:32:41 8 Q. Or perhaps, if they were produced in a
10:32:43 9 lawsuit, you could also have access to them that way;
10:32:47 10 right?

10:32:47 11 A. Well inasmuch as the company has them. But
10:32:50 12 the company typically doesn't have the FDA review
10:32:52 13 documents.

10:32:53 14 Q. Do you know if 3M does?

10:32:54 15 A. No.

10:32:56 16 Q. Have you asked them?

10:32:58 17 Is that a type of material you would have
10:33:01 18 wanted to review in this case?

10:33:04 19 A. No. I looked at the 510(k) submissions --

10:33:04 20 Q. So the decision --

10:33:06 21 A. -- and -- and -- excuse me -- and in the
10:33:08 22 510(k)s there's also documentation of FDA's
10:33:10 23 interaction with the company, the letters that FDA has
10:33:12 24 written to the company, the responses by the company,
10:33:15 25 so there's some -- there's important information

10:33:21 1 contained there. But what I'm referring to is, you
10:33:25 2 know, where is the review of the FDA reviewer of the
10:33:31 3 submission, and that -- that I don't have.

10:33:33 4 Q. Okay. And I had asked you some questions
10:33:37 5 about the 510(k) approval process and what the FDA did
10:33:41 6 or did not do or did or did not find during that
10:33:43 7 process, and those were questions that you would be
10:33:45 8 unable to answer unless you had the decision-making
10:33:48 9 documents; correct?

10:33:48 10 A. No. I would say no, because the fun --
10:33:52 11 you --

10:33:54 12 Inasmuch as we're talking about policy and
10:33:57 13 procedure, it's all the same no matter what the 510(k)
10:34:00 14 is. So when I say -- when you asked, for example,
10:34:03 15 would they have evaluated a new indication for safety
10:34:06 16 and effectiveness related to this difference and my
10:34:10 17 answer is there's no question because that's -- that's
10:34:13 18 invariable in regard to policy and procedure. You
10:34:16 19 must.

10:34:16 20 Q. Okay. Well this is good because I can ask
10:34:18 21 you this question, and this is -- we're going to go
10:34:21 22 back to something we talked about before, which is:
10:34:23 23 What did the FDA do in order to determine that the
10:34:26 24 Bair Hugger 500 series deployment into ORs did not
10:34:31 25 pose a new question of safety or effectiveness?

10:34:35 1 A. Well that's FDA's analysis of the new
10:34:37 2 labeling compared to the old labeling. In addition,
10:34:40 3 bringing to bear, as I mentioned, all other infor --
10:34:42 4 information at their disposal on the use of these
10:34:45 5 types of products.

10:34:46 6 Q. You don't know what that information was.

10:34:50 7 A. Well I didn't amass it, I didn't collect it
10:34:54 8 and -- and evaluate it for purposes of any particular
10:34:59 9 510(k).

10:34:59 10 Q. Nor were you provided the decision-making
10:35:02 11 documentation from the FDA that was produced by --
10:35:06 12 that was created by the FDA. That has not been
10:35:08 13 provided to you in this litigation.

10:35:11 14 A. No. But I might add that this type of
10:35:14 15 evolution of indication for use is -- is not
10:35:18 16 extraordinary. I'll call it almost commonplace that
10:35:22 17 devices of this type and others will find their usage
10:35:30 18 expansion -- expanded into different hospital
10:35:36 19 settings, home-use settings, various settings. So
10:35:39 20 it's not --

10:35:40 21 It wasn't remarkable with me at all that the
10:35:43 22 Bair Hugger evolved, in regard to its intended use and
10:35:47 23 indications for use, into the OR setting.

10:35:50 24 MR. BANKSTON: Okay. Object as
10:35:51 25 non-responsive.

10:35:52 1 Q. All I really wanted to know was in your
10:35:55 2 materials review, were you provided the decision-
10:35:58 3 making documents for the 500 series Bair Hugger?

10:36:00 4 A. No.

10:36:01 5 Q. Okay.

10:36:12 6 THE WITNESS: Maybe we can take a break in
10:36:15 7 just a minute.

10:36:15 8 MR. BANKSTON: Absolutely. Sure, we can do
10:36:16 9 that.

10:36:16 10 MS. EATON: Thank you.

10:36:18 11 THE REPORTER: Off the record, please.

10:51:10 12 (Recess taken.)

10:51:10 13 BY MR. BANKSTON:

10:51:16 14 Q. All right, Mr. Ulatowski, first of all, you
10:51:20 15 understand not --

10:51:22 16 We didn't really get to this at the
10:51:22 17 beginning. I just want to make sure you are clear.
10:51:26 18 You understand that I represent about 2,000 plaintiffs
10:51:28 19 who have brought suit against 3M.

10:51:31 20 A. Right, I -- I -- I -- I know. I think it's
10:51:33 21 up to 2,000 right now, yeah.

10:51:35 22 Q. Okay. Today I'm here --

10:51:37 23 First of all, you'll agree with me this
10:51:39 24 lawsuit, it's an important matter, it's an important
10:51:41 25 thing to get right.

10:51:42 1 A. Certainly.

10:51:43 2 Q. It's something to treat with seriousness,
10:51:47 3 solemnity, all that sort of stuff.

10:51:49 4 A. Of course.

10:51:49 5 Q. Sure. And in doing your report, you were,
10:51:54 6 say, conscientious about reviewing information
10:51:57 7 effectively, assembling materials, coming to re --
10:52:02 8 opinions based on the materials that you reviewed.

10:52:04 9 A. Yes.

10:52:05 10 Q. Okay. And your report lists, we've talked
10:52:08 11 about -- and we'll talk about Exhibit 2 -- lists some
10:52:13 12 materials that you've relied on.

10:52:16 13 A. Correct.

10:52:16 14 Q. And that would be, you would agree with me,
10:52:17 15 the sum total of things that you have reviewed,
10:52:20 16 documentary material that form the basis of your
10:52:22 17 opinions in this lawsuit.

10:52:23 18 A. Yes.

10:52:24 19 Q. Okay. You took care in reviewing those
10:52:28 20 documents.

10:52:28 21 A. I tried to, yes.

10:52:29 22 Q. From what I can tell, you reviewed 12 expert
10:52:33 23 reports.

10:52:38 24 A. I'll turn to that so I can --

10:52:40 25 Q. Sure.

10:52:52 1 A. Right, concentrating on Dr. David and -- and
10:52:56 2 Bill Jarvis, yes.

10:52:58 3 Q. Okay. Twelve of those expert reports you
10:53:02 4 have reviewed.

10:53:03 5 A. To some degree.

10:53:05 6 Q. I'm not sure I'm understanding what you're
10:53:09 7 meaning. I understand that with Dr. David and Dr.
10:53:09 8 Jarvis, you probably reviewed them very closely to
10:53:12 9 give opinions about what they're saying, but with the
10:53:15 10 other ones, those are reports you've read; right?

10:53:17 11 A. Yes. And the reason I said that was I -- I
10:53:21 12 focused on Dr. David because he was making regulatory
10:53:25 13 assertions, Dr. Jarvis because he also alluded to some
10:53:31 14 regulatory-related information. And -- and, you know,
10:53:34 15 I think I know Bill Jarvis, but it's been a long time.

10:53:39 16 Q. Okay. In coming to determine who you need
10:53:41 17 to concentrate on, who is saying what, you have to
10:53:44 18 read the report.

10:53:45 19 A. Yes. And I --

10:53:46 20 What I do is I will look at the reports, the
10:53:49 21 topic matters, first looking for any particular
10:53:55 22 relevance to what my focus is, and -- and then
10:54:01 23 proceeding. So things, for example, of airflow and
10:54:04 24 things of that -- well that's not really within my
10:54:06 25 wheelhouse, so I wouldn't spend a lot of time on that.

10:54:09 1 Q. And when reading those reports, you
10:54:11 2 discovered that they contained information that wasn't
10:54:12 3 in your wheelhouse and therefore you don't concentrate
10:54:15 4 on those reports in giving your opinions.

10:54:17 5 A. Correct.

10:54:18 6 Q. You've read them though.

10:54:20 7 A. Yes.

10:54:20 8 Q. Okay. You have also reviewed 44
10:54:24 9 depositions; correct?

10:54:25 10 A. Yeah. Yes. Yes.

10:54:27 11 Q. Okay.

10:54:28 12 A. A lot of depositions.

10:54:29 13 Q. I take it that the -- the sort of chuckle
10:54:31 14 was because it's a huge amount of material.

10:54:33 15 A. Well depositions are --

10:54:34 16 You got to slug through them. And, you
10:54:38 17 know, there have been depositions of the same people
10:54:40 18 over time that, you know, it --

10:54:43 19 But they're all important.

10:54:45 20 Q. Right. All 44 of those depositions, all the
10:54:47 21 testimony given that you've reviewed, you cited it,
10:54:50 22 that there were things you wanted to review because
10:54:53 23 their testimony is important.

10:54:54 24 A. Certainly.

10:54:55 25 Q. Certainly.

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10:54:55 1 Those depositions, some of them are 300 or
10:54:59 2 plus pages; correct?

10:55:00 3 A. Or more, yes.

10:55:01 4 Q. Correct. So there's been a lot of testimony
10:55:04 5 given in this case about the issues you discuss in
10:55:06 6 your report.

10:55:07 7 A. Yes, there has been.

10:55:08 8 Q. Okay. You also have reviewed over 200
10:55:12 9 different medical articles.

10:55:15 10 A. Yes. I received early on in Walton, I
10:55:18 11 think, or -- or Johnson, copies of relevant literature
10:55:24 12 pro and con. I may not necessarily review each and
10:55:29 13 every article word for word, but I certainly look at
10:55:32 14 the abstract, look at conclusions, then delve into
10:55:36 15 particular ones as my interest takes me.

10:55:38 16 Q. Okay. So some of those medical articles you
10:55:41 17 may have just read, while some of them you may have
10:55:44 18 done a pretty thorough review on if they were
10:55:47 19 something that was close to your report.

10:55:49 20 A. No, close to the area of my interest. So if
10:55:53 21 it was particular -- pro and con. So if it was
10:55:56 22 relevant to a particular topic cited in a 510(k),
10:56:07 23 cited to FDA in one way or another, yes, those I would
10:56:11 24 pay attention to. Also, what experts referred to in
10:56:15 25 their report.

10:56:16 1 Q. Uh-huh. Well let me make sure I understand.
10:56:19 2 When you say "what the experts referred to in their
10:56:21 3 report," is that additional materials you've reviewed
10:56:24 4 on top of what's listed in Exhibit B?

10:56:26 5 A. No, that -- that's all incorporated here.

10:56:28 6 Q. Okay. Now those medical articles, those are
10:56:32 7 technical publications; correct?

10:56:33 8 A. Yes.

10:56:34 9 Q. The -- the average layman off the street is
10:56:37 10 going to have some difficulty with those publications.

10:56:41 11 A. Perhaps.

10:56:42 12 Q. I mean that's part of the reason why we have
10:56:44 13 expert witnesses, right, is to have people who can
10:56:46 14 read those kind of publications.

10:56:48 15 A. Who have particular expertise in the subject
10:56:51 16 matter.

10:56:52 17 Q. Okay. And when reading those articles and
10:56:55 18 reviewing them and using them to support your opinions
10:56:57 19 in this case, you attempted to be conscientious about
10:56:59 20 reviewing them correctly and understanding their
10:57:01 21 conclusions.

10:57:02 22 A. Right. Because in my experience at FDA
10:57:04 23 and -- and now as consultant, I -- it was my history
10:57:09 24 and process and policy to evaluate the information
10:57:13 25 provided, whether pro or con, to get a sense of -- of

10:57:18 1 what it was saying, and -- and then to proceed
10:57:21 2 accordingly.

10:57:21 3 Q. Okay. Another thing you reviewed was
10:57:26 4 hundreds of litigation-produced documents.

10:57:31 5 A. Yes. A lot of documents.

10:57:32 6 Q. Okay. Thousands of pages.

10:57:35 7 A. Right. Not necessarily every page in
10:57:38 8 detail. For example, some documents may contain
10:57:43 9 information that's not particularly relevant to -- to
10:57:46 10 my focus area, regulatory focus, so you can -- you can
10:57:51 11 typically identify that early on and -- and then move
10:57:55 12 on.

10:57:55 13 Q. Okay. Are there --

10:57:56 14 Now these materials that are cited in your
10:57:58 15 report, would you characterize these as materials that
10:58:04 16 you are relying on for your report and there are other
10:58:08 17 materials not listed here that you've reviewed but did
10:58:11 18 not rely on, or does this list constitute everything
10:58:15 19 you've reviewed in the case?

10:58:17 20 A. Well, as far as documents are concerned,
10:58:25 21 this list should contain everything upon which -- and
10:58:28 22 does contain everything upon which my report is based.
10:58:32 23 I don't know if you're implying that do I -- do I rely
10:58:36 24 upon other things. You know, certainly I have my own
10:58:41 25 expertise and experiences over my lifetime at FDA

10:58:45 1 and -- and -- and now as a consultant.

10:58:46 2 Q. Now my question was more directed towards
10:58:49 3 were there materials that you found and read or were
10:58:52 4 provided to you and you read that, once you looked at
10:58:55 5 them and read them, said, okay, no, this is absolutely
10:58:58 6 no way even relevant to this case, this is not
10:59:00 7 something I'm relying on, it's not on that list. So
10:59:04 8 you may have read it but it has no relevance to the
10:59:06 9 case.

10:59:06 10 A. No. I expect ev -- everything I've been
10:59:10 11 given ends up on this list.

10:59:12 12 Q. Okay. Now one of the other things that you
10:59:13 13 have done in this case is there was a subpoena served
10:59:16 14 on you; correct?

10:59:17 15 A. Yes.

10:59:18 16 Q. Okay. And it requested certain items.

10:59:19 17 A. Yes.

10:59:20 18 Q. And you were conscientious -- conscientious
10:59:23 19 and treated that with seriousness in responding to it.

10:59:26 20 A. Yes.

10:59:26 21 Q. One of the things that it asked you for was
10:59:29 22 invoices relating to the work that you have performed
10:59:32 23 on the Bair Hugger.

10:59:33 24 A. Yes.

10:59:34 25 Q. Okay. And you produced at least some

10:59:36 1 invoices of work you've performed.

10:59:38 2 A. Yes.

10:59:39 3 Q. Okay. And we talked this morning that you
10:59:42 4 didn't have a direct memory of what those invoices
10:59:47 5 said and how many there were, but the invoices were
10:59:47 6 there and we can refer to them to determine how much
10:59:50 7 work you've done on this case.

10:59:52 8 A. Yes. I don't prepare the invoices. I don't
10:59:54 9 submit the time to the clients. That's done by NSF
10:59:59 10 Health Sciences in this case.

11:00:00 11 Q. Okay. I have taken a look at the response
11:00:07 12 to the subpoena and looked at the hours that have been
11:00:12 13 submitted and I wanted to talk to you a little bit
11:00:14 14 about that.

11:00:15 15 A. Sure.

11:00:15 16 Q. From the subpoenas that we have, there is
11:00:18 17 work being billed from you in January, February, March
11:00:21 18 and April; correct?

11:00:24 19 A. Okay.

11:00:24 20 Q. Okay? In January there was eight -- eight
11:00:29 21 and a quarter, 8.25 hours, and that is labeled as
11:00:32 22 "Document review." When you say "Document review,"
11:00:36 23 what does that entail?

11:00:37 24 A. It can mean a lot of different things:
11:00:39 25 individual documents, depositions. Typically, I -- I

11:00:43 1 may say "depositions" and not "document review," so it
11:00:46 2 could be a number of things.

11:00:47 3 Q. Okay. So we have eight and a quarter hours
11:00:49 4 in January. In February there's an hour and a half of
11:00:52 5 billing, and then in March there's two and a quarter
11:01:00 6 hours of billing, and in April there's 31 and three-
11:01:04 7 quarters hours of billing, and that is labeled "MDL
11:01:09 8 report." And so I take it that there is various
11:01:13 9 things that you had to do in order to end up with the
11:01:18 10 report that we have. The hundred-page or so report
11:01:21 11 that you did took work and effort into making it.

11:01:23 12 A. Yes.

11:01:24 13 Q. Okay. Can you give me an estimate sitting
11:01:26 14 here in terms of the drafting process, of drafting the
11:01:29 15 report -- not the review of documents, not any of that
11:01:32 16 sort of stuff -- in terms of just how long does it
11:01:35 17 take Mr. Ulatowski to write a one-hundred-page report?
11:01:39 18 How long does that take?

11:01:40 19 A. That would be incorporated in the 31 hours.

11:01:43 20 Q. Okay. And I understand that. So what I'm
11:01:45 21 trying to say is in that 31 hours, when you're talking
11:01:49 22 about your MDL report, there are things involved in
11:01:51 23 that billing that are not simply typing the report.

11:01:53 24 A. Well there may be, yes. There often are.

11:01:56 25 Q. Okay. So in other words, it did not take

11:01:58 1 you 31.75 hours to type the report.

11:02:05 2 A. Could. Could have but -- but may not have.

11:02:08 3 Q. Okay.

11:02:09 4 MR. BANKSTON: I'm sorry, do you need to --

11:02:10 5 MS. EATON: Yeah. Just if I may, what I

11:02:13 6 understood we were to produce is invoices of his work

11:02:16 7 specific to the MDL, and so the invoices I produced

11:02:20 8 did not include prior time that he had reviewed

9 materials.

10 MR. BANKSTON: Okay. Well if we need to --

11:02:23 11 MS. EATON: Just to clarify.

11:02:25 12 MR. BANKSTON: If we need to get what your

11:02:27 13 opinion on that is, well we have it on the record now.

11:02:29 14 MS. EATON: It isn't an opinion, it's a fact

11:02:33 15 I'm letting you know --

16 MR. BANKSTON: Well I -- I --

11:02:33 17 MS. EATON: -- for your purpose.

11:02:33 18 MR. BANKSTON: I don't have it in front of

11:02:35 19 me. You don't have it in front of you either.

20 You're not testifying today. I'm asking him

11:02:38 21 questions. I appreciate your input into the

11:02:39 22 deposition.

11:02:39 23 Q. But as far as what you have produced to us

11:02:41 24 in terms of writing this MDL report, you have produced

11:02:43 25 to us 44 hours of billing.

11:02:45 1 A. Right. And that was my understanding, it
11:02:48 2 was the MDL. It wasn't the prior work done for
11:02:50 3 Greenberg Traurig or -- or -- or this law firm on the
11:02:57 4 same topic --

11:02:57 5 Q. Correct.

11:02:58 6 A. -- area.

11:02:58 7 Q. Okay. So let's just talk about your work in
11:03:02 8 this phase of the proceedings; in other words, since
11:03:06 9 you have been brought to bear on the MDL side of it.
11:03:09 10 Okay? You understand that of the expert reports that
11:03:12 11 you reviewed in this case, nearly all of them were
11:03:15 12 produced in the MDL.

11:03:17 13 A. Uh-huh.

11:03:18 14 Q. Okay.

11:03:19 15 A. Yes.

11:03:19 16 THE REPORTER: Your answer?

11:03:20 17 THE WITNESS: Yes.

11:03:21 18 Q. Of the depositions that you reviewed, the
11:03:23 19 great majority of them were done in the MDL.

11:03:25 20 MS. EATON: Object to the form of the
11:03:26 21 question.

11:03:27 22 A. The new ones.

11:03:29 23 Q. Uh-huh.

11:03:30 24 A. There are older ones from the same people on
11:03:32 25 the same topic area, yes.

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11:03:34 1 Q. There are some, correct. Right. What I'm
11:03:36 2 asking you is: The majority of the depositions you've
11:03:37 3 reviewed have been in the MDL. Would you agree with
11:03:41 4 that?

11:03:41 5 A. Correct.

11:03:42 6 Well in the MDL, yes. There were
11:03:44 7 depositions specific to the time period for the MDL.

11:03:47 8 Q. What I'm asking is: There is a total pool
11:03:50 9 of depositions you reviewed, some of them occurred in
11:03:53 10 two prior cases a couple years ago and some of them
11:03:55 11 occurred in this MDL.

11:03:57 12 A. Yes.

11:03:57 13 Q. The vast majority of them occurred in the
11:03:59 14 MDL. Do you agree with that?

11:04:01 15 MS. EATON: Object to the form of the
11:04:02 16 question.

11:04:02 17 A. You know, I couldn't say that's the fact,
11:04:04 18 but I know there were numerous depositions, prior
11:04:06 19 depositions, same people, same topic areas, and then
11:04:10 20 the newer depositions that I had to look through to
11:04:15 21 update my -- my report in the MDL.

11:04:18 22 Q. Okay. So we have also medical journal
11:04:24 23 articles, and any medical journal article that is not
11:04:27 24 listed in your Walton or Johnson report is something
11:04:29 25 that would have been new and reviewed in the MDL.

11:04:35 1 MS. EATON: Object to the form of the
11:04:36 2 question.

11:04:37 3 A. If -- if provided and not previously
11:04:40 4 provided.

11:04:41 5 Q. Well if it wasn't listed as something you
11:04:42 6 reviewed in Walton/Johnson, you didn't review it in
11:04:45 7 Walton and Johnson; correct?

11:04:47 8 A. Probably not.

11:04:48 9 Q. Okay. You think there's a reasonable
11:04:51 10 possibility there are materials that you reviewed in
11:04:54 11 pre -- in preparing your opinions in Walton/Johnson
11:04:56 12 that you did not disclose?

11:04:58 13 A. No. I'm saying I was provided material in
11:05:00 14 Walton/Johnson. If there was new material provided in
11:05:03 15 the MDL, you know, that was the new material to
11:05:05 16 evaluate under the MDL.

11:05:07 17 Q. Correct. So if the material was not listed
11:05:10 18 in your Walton or Johnson report, then it must be part
11:05:15 19 of this 44 hours.

11:05:15 20 A. Perhaps.

11:05:16 21 Q. I -- I don't --

11:05:17 22 I'm trying to understand why when you say
11:05:19 23 "perhaps." Are you saying that there are articles
11:05:20 24 that you did not review -- or that you did review to
11:05:24 25 form your Walton/Johnson opinions that you did not

11:05:27 1 disclose in your report in Walton/Johnson?

11:05:29 2 A. Well I never -- never produced a report.

11:05:32 3 You know, I don't know the status of those, but --

11:05:34 4 Q. Are -- I'm sorry. Are you saying you did
11:05:36 5 not make a report in Walton?

11:05:37 6 A. I did. I did. I just don't know the status
11:05:39 7 of it as far as if it was ever formally produced. You
11:05:43 8 know, I'm looking at my attorney, but --

11:05:45 9 Q. Okay. I'll represent to you I got a copy of
11:05:48 10 it --

11:05:48 11 A. Okay.

11:05:48 12 Q. -- so it exists, it's out there.

11:05:49 13 A. Okay.

11:05:50 14 Q. What I'm asking is: When you gave that
11:05:52 15 report and included your references in it, there's --
11:05:54 16 there's not materials out there that you reviewed that
11:05:56 17 you failed to disclose in that report.

11:05:58 18 A. No. Everything was in there, in that
11:06:01 19 disclosure.

11:06:01 20 Q. Okay. So --

11:06:02 21 A. Now I can't say, and it's probably not the
11:06:04 22 case, that in the interim between the Walton report
11:06:08 23 and the MDL I wasn't provided something else until
11:06:13 24 January of this year. You know, I just -- I don't
11:06:16 25 think so, but --

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11:06:17 1 Q. Okay. Another thing that you reviewed was
11:06:22 2 hundreds of internal documents; correct?

11:06:25 3 A. A lot of those were duplicates of
11:06:28 4 previously-reviewed material.

11:06:30 5 MR. BANKSTON: Okay. Objection,
11:06:31 6 non-responsive.

11:06:31 7 Q. Sir, in this case you've re -- you've
11:06:32 8 reviewed hundreds of internal documents.

11:06:37 9 A. Duplicate documents, yes.

11:06:42 10 Q. The documents on that list that say 3MBH
11:06:48 11 that are related to this MDL, it's your contention
11:06:51 12 that none of those are new documents?

11:06:52 13 A. Well I think some of them are, but a lot of
11:06:54 14 them are -- are duplicates of what was produced in
11:06:57 15 Walton and Johnson.

11:06:58 16 Q. Okay. Well we could easily --
11:06:59 17 That's something you could easily find out
11:07:01 18 if you needed to.

11:07:02 19 A. Well I'd look to them to do that kind of
11:07:05 20 search.

11:07:05 21 Q. Sure. Sure.

11:07:06 22 A. Yeah.

11:07:06 23 Q. In other words, your report lists out your
11:07:08 24 materials in such a way that it could be determined
11:07:11 25 what has been reviewed since the MDL -- your work

11:07:14 1 started in the MDL.

11:07:15 2 A. Right. As I -- as I produced -- began to
11:07:18 3 produce my MDL report I had, because I didn't want to
11:07:26 4 reproduce -- go from the -- from the first step again,
11:07:34 5 I looked at my Walton report and Johnson to see what I
11:07:39 6 had done, what reference documents I had, and those
11:07:42 7 were -- those are different Bates formats. So when I
11:07:47 8 produced the MDL, even though relying on the same
11:07:50 9 documents, we had to translate them into MBH Bates
11:07:54 10 numbers.

11:07:54 11 Q. Okay. So the list that was created in your
11:07:59 12 report, are you saying that those are simply the
11:08:02 13 documents that are in your Walton report with new
11:08:04 14 Bates numbers?

11:08:05 15 A. Many of them are.

11:08:06 16 Q. Okay.

11:08:07 17 A. Yes. Not all of them.

11:08:08 18 Q. Okay. That's what I want to make sure I
11:08:12 19 understand. There is a pool of documents that you
11:08:12 20 have not seen in Walton and Johnson that you did
11:08:15 21 review for those -- this case.

11:08:17 22 A. Yes. For example, when I reviewed Dr.
11:08:21 23 David's report, he had reference to a number of
11:08:24 24 documents. I requested all his reference documents.
11:08:29 25 Some I -- I don't think I had seen before, --

11:08:31 1 Q. Okay.

11:08:32 2 A. -- some I had seen before.

11:08:33 3 Q. Okay. Then with respect to the expert
11:08:38 4 reports you reviewed, you'll agree with me that the
11:08:40 5 overwhelming majority of those expert reports did not
11:08:44 6 exist at the time of Walton and Johnson.

11:08:46 7 A. Right, inasmuch as they were produced for
11:08:48 8 the MDL.

11:08:49 9 Q. Okay. So we have the majority of the expert
11:08:54 10 reports, a large sum of the depositions, any medical
11:09:00 11 articles that are not contained in your original
11:09:02 12 Walton report, and any new internal documents. All of
11:09:06 13 that was reviewed in this MDL.

11:09:09 14 A. Right, in one -- one form or another, yes.

11:09:12 15 Q. Okay. So it's your sworn testimony that you
11:09:17 16 were able to review all of those materials, those
11:09:20 17 approximately 10 expert reports, those potentially 20
11:09:27 18 or so depositions -- let's just go ahead and make it
11:09:30 19 fair; there's 44 depositions on your report, let's
11:09:32 20 just go ahead and call it 20, you can say the majority
11:09:35 21 were from Walton and Johnson even though we know
11:09:38 22 that's not the case -- and there's some medical
11:09:41 23 journal articles and internal documents, and you read
11:09:43 24 conscientiously those documents and you drafted a
11:09:47 25 one-hundred-plus-page report and you did that in 44

11:09:50 1 hours.

11:09:51 2 MS. EATON: Object to the form of the
11:09:52 3 question. It mischaracterizes --

11:09:55 4 We have the dates of the depositions if
11:09:59 5 you'd like to see them. And I would also like to
11:09:59 6 clarify for the record that there was time spent in
11:10:04 7 May 2017, I don't believe we have an invoice yet, or
11:10:06 8 at least we didn't at the time we prepared the
11:10:08 9 subpoena.

11:10:08 10 MR. BANKSTON: Okay. That's testimony and
11:10:13 11 he can tell me that.

11:10:14 12 Q. Do you remember the question, sir?

11:10:16 13 A. Yes. I reviewed the documents to the degree
11:10:19 14 I found necessary, and I described instances where I
11:10:24 15 did not find it necessary to review the entire expert
11:10:27 16 report because it wasn't germane to the focus of my
11:10:30 17 report. In regard to deposition testimony, as I -- as
11:10:35 18 I coursed through depositions, I -- I can identify
11:10:39 19 areas that, through word searches and other, that are
11:10:42 20 relevant to what I'm looking for. And exhibits.
11:10:46 21 So --

11:10:47 22 And it astounds me in many regards that --
11:10:52 23 that some experts take enormous amounts of time to go
11:10:54 24 through information. It's just -- I don't know how
11:10:57 25 they do it. I'm -- I'm a very quick worker, so I'm --

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11:11:02 1 I'm selective in regard to what I look at in regard to
11:11:07 2 the material I'm provided. I focus in on what I'm
11:11:11 3 interested in, what's germane to what I'm -- the focus
11:11:15 4 of my expertise, my report, what I was asked to do.
11:11:18 5 And understanding that, yes, all the information
11:11:20 6 provided to me may have value, so I take a look at it
11:11:24 7 to get the gist of what's going on to the degree
11:11:27 8 necessary, and then I move on.

11:11:29 9 Q. Okay. You --

11:11:32 10 We had talked about this is an important
11:11:34 11 matter, you take it seriously.

11:11:35 12 A. Yes.

11:11:36 13 Q. Yeah. But in terms of these materials, you
11:11:41 14 didn't conscientiously review their totality; did you?
11:11:43 15 I mean if we're talking about word searches and speed
11:11:46 16 reading, we're not talking about a conscientious
11:11:48 17 review of these materials; are we?

11:11:50 18 MS. EATON: Object to the form of the
11:11:51 19 question.

11:11:51 20 A. It certainly is a matter of how you may
11:11:53 21 characterize it.

11:11:55 22 Q. I'm just wondering if you want our clients
11:11:58 23 to believe that it's physically possible to have read
11:12:02 24 the amount of material you claim to rely on in this
11:12:04 25 case in 44 hours, plus draft a one-hundred-page

11:12:08 1 report.

11:12:08 2 MS. EATON: Object to the form of the
11:12:09 3 question.

11:12:09 4 A. It is what it is.

11:12:14 5 Q. Let's jump a bit into our conversation about
11:12:24 6 how devices are used. The FDA does not, when making
11:12:33 7 the decisions about the Bair Hugger 200, 500, 700
11:12:36 8 series, making decisions about both the clearance of
11:12:39 9 the product and its continuing monitoring of the
11:12:41 10 product, it does not have a lot of information about
11:12:44 11 exactly how the product is used. Would you agree with
11:12:48 12 me there?

11:12:52 13 A. Not necessarily. There is information
11:12:55 14 FDA -- and I've alluded to this already or stated
11:13:00 15 directly, that FDA has at its disposal and it utilizes
11:13:04 16 not only submissions made to it, it has postmarketing
11:13:07 17 information that it monitors, including clinical
11:13:10 18 literature or other literature, other submissions made
11:13:14 19 by competitors who -- of like devices, MDR reports for
11:13:21 20 example, and other information that's brought to bear.
11:13:23 21 So FDA does -- to the extent it can, monitors the
11:13:28 22 products while in the marketplace.

11:13:30 23 Q. What information did you review in this
11:13:32 24 case, if any, that would give the FDA any indication
11:13:35 25 that any Bair Hugger was going to be deployed in an

11:13:39 1 orthopedic surgery and implant situation?

11:13:44 2 A. Well from the submissions, as I've stated,
11:13:48 3 there's reference to OR use. As far as particular
11:13:53 4 orthopedic use, well that's -- that's, you know, a
11:13:57 5 subset of OR use. So I don't think orthopedic use was
11:14:02 6 discussed in the 505. But again, FDA has information
11:14:09 7 to bring to bear about the current usage of products,
11:14:12 8 being knowledgeable about the usage even in the
11:14:15 9 absence of submission data and information.

11:14:19 10 Q. Okay. I -- I realize when asking this
11:14:28 11 question we had talked earlier, I know you're not an
11:14:28 12 expert in orthopedic surgery and I'm not asking you to
11:14:31 13 be one for this question, but I -- I -- I think you'd
11:14:33 14 agree with me that from reviewing the reports you've
11:14:36 15 reviewed in this case and from reviewing the
11:14:38 16 deposition testimony in this case, you will agree with
11:14:42 17 me orthopedic surgeries have some very unique
11:14:44 18 characteristics.

11:14:48 19 A. Many unique characteristics and many
11:14:51 20 similarities.

11:14:52 21 Q. Sure. And you are aware of the unusual
11:14:58 22 sensitivity of orthopedic surgeries to post-surgical
11:15:02 23 infections.

11:15:04 24 A. Post-surgical infections occur in orthopedic
11:15:07 25 surgery, yes.

11:15:07 1 Q. They occur in a lot of surgeries; don't
11:15:10 2 they?

11:15:10 3 A. Absolutely.

11:15:10 4 Q. Okay. What I'm asking you is: You
11:15:12 5 understood from reading your depositions, your reports
11:15:14 6 and everything else you reviewed in this case, you
11:15:16 7 understood that orthopedic surgeries were unusually
11:15:19 8 sensitive to post-surgical infections.

11:15:22 9 A. Well I --

11:15:22 10 MS. EATON: Object to the form of the
11:15:23 11 question.

11:15:24 12 A. Yes. But I know -- I know that from other
11:15:28 13 experience.

11:15:28 14 Q. Sure. And maybe you knew that even before
11:15:29 15 you came onto this case; correct?

11:15:30 16 A. Absolutely.

11:15:31 17 Q. Okay.

11:15:31 18 A. I mean I have been engaged -- you know,
11:15:34 19 that's -- it's one example, but in hip implant surgery
11:15:37 20 cases, knee surgery cases, and while at FDA being
11:15:42 21 involved in many, many companies creating medical
11:15:46 22 devices used in orthopedic surgery and the problems
11:15:49 23 encountered. So it wasn't new information for us.

11:15:51 24 Q. Sure. And so you understood, for example,
11:15:53 25 that the surgeons in an orthopedic implant surgery do

11:15:55 1 not dress like surgeons in other surgeries.

11:15:59 2 A. That's evolved over time and -- and

11:16:00 3 currently, yes. It's -- it's changing even as we

11:16:03 4 speak.

11:16:03 5 Q. And you understood that orthopedic surgeries

11:16:05 6 as opposed to general surgeries present unique

11:16:08 7 clinical questions of safety.

11:16:10 8 MS. EATON: Object to the form of the

11:16:11 9 question.

11:16:12 10 A. I don't know if it's unique questions of

11:16:14 11 safety. I think it's -- there's -- there's -- there's

11:16:17 12 different aspects, but it's -- it's similar questions

11:16:20 13 being asked about the infectious process, the

11:16:24 14 organisms, the environment of use. There's

11:16:28 15 particular --

11:16:29 16 As you stated and as I confirmed, yes,

11:16:31 17 there's unique aspects to orthopedic surgery. They're

11:16:35 18 surgeries of a type that's particularly invasive, it's

11:16:38 19 prolonged, aspects like that.

11:16:41 20 Q. Okay. For instance, what's safe in a

11:16:49 21 vascular surgery might not be safe in an orthopedic

11:16:53 22 surgery.

11:16:53 23 MS. EATON: Object to the form of the

11:16:54 24 question.

11:16:57 25 A. I guess we'd have to talk about some spec --

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11:17:01 1 specifics here, because there's a lot of similarities
11:17:03 2 in the types of medical devices used in all surgeries.
11:17:08 3 Yes, there's particular instruments used in orthopedic
11:17:10 4 surgeries, there's, you know, all the saws and
11:17:12 5 paraphernalia, but -- but there's other similar types
11:17:15 6 of devices used as well.

11:17:17 7 Q. Okay. I understand that both surgeries have
11:17:20 8 tools they use in each of the surgeries, and I
11:17:22 9 understand that some of those overlap and some of them
11:17:25 10 don't.

11:17:25 11 A. That's correct.

11:17:27 12 Q. Right. But what I'm really asking is a
11:17:28 13 product, a device that may be safe for a vascular
11:17:32 14 surgery, there is the potential that it may not be
11:17:34 15 safe for an orthopedic surgery.

11:17:37 16 MS. EATON: Object to the form of the
11:17:38 17 question.

11:17:38 18 A. I guess it depends on the particular
11:17:40 19 vascular surgery or -- or cardiac surgery, because --
11:17:45 20 or neurosurgery, because they can be very, very
11:17:49 21 intensive and have a potential for infection as well.
11:17:51 22 So --

11:17:51 23 Q. Sure. So in fact there may be things that
11:17:53 24 are safe in an orthopedic surgery that are not safe in
11:17:56 25 a vascular surgery.

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11:17:58 1 MS. EATON: Object to the form of the
11:18:00 2 question.

11:18:00 3 A. Potentially.

11:18:01 4 Q. Okay. Would you also agree with me that the
11:18:04 5 insufficiency of information about how devices are
11:18:08 6 actually used once they're on the market, that that
11:18:11 7 insufficiency of information adversely affects the
11:18:16 8 ability of the FDA to evaluate devices for safety?

11:18:25 9 A. Well the -- the setup is the insufficiency
11:18:28 10 of information, and I -- I don't agree that there's an
11:18:32 11 insufficiency of information within FDA on the -- on
11:18:38 12 the usage of -- of the types of product it -- it
11:18:42 13 evaluates and monitors. I think -- I think, unknown
11:18:46 14 to lawyers or -- or the public in general, FDA has
11:18:51 15 considerable knowledge about the use of products. FDA
11:18:55 16 employs clinicians, FDA employs people who are fresh
11:19:01 17 from -- from hospital employment, trained
11:19:07 18 orthopedists, so I -- I think it would be an
11:19:09 19 overstatement about FDA's lack of knowledge about use
11:19:13 20 of products.

11:19:13 21 Q. So in other words, I think what you would
11:19:16 22 say is that insufficiency of information about how
11:19:17 23 devices have -- are being used once they're on the
11:19:20 24 market, that has not been a major problem for the FDA.

11:19:23 25 A. We'd have to talk specifics, I think, in

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11:19:26 1 regard to particular products, but I think as a

11:19:29 2 general rule that's --

11:19:30 3 I think it's a dangerous statement to make.

11:19:31 4 Q. Okay. I want you to take Exhibit 1, and if

11:19:36 5 you could flip to page 80 for me.

11:19:55 6 All right, sir. I have directed you to page

11:19:58 7 80 of the IOM report --

11:20:00 8 A. Uh-huh?

11:20:01 9 Q. -- which was a report directed to be created

11:20:02 10 by the commissioner of the FDA to examine the 510(k)

11:20:07 11 process; correct?

11:20:08 12 A. Right.

11:20:08 13 Q. Okay. Do you see finding 4.6?

11:20:16 14 A. Yes, I see what's stated.

11:20:18 15 Q. Okay. And finding 4.6 states,

11:20:21 16 "Insufficiency of information about how devices are

11:20:24 17 used and perform once they're on the market adversely

11:20:28 18 affects the ability of the FDA to evaluate devices'

11:20:32 19 intended uses, indications for use, and substantial

11:20:36 20 equivalence in a 510(k) review."

11:20:38 21 Is it your testimony today that that kind of

11:20:40 22 statement is what you meant by a dangerous statement?

11:20:42 23 A. It's a broad-based statement that has to be

11:20:47 24 applied and evaluated to specific instances where it

11:20:51 25 may be false, entirely false.

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11:20:52 1 Q. Okay. I believe you are of the opinion that
11:20:57 2 the 510(k) submission for the model 500 included valid
11:21:01 3 scientific evidence for the Bair Hugger's use in
11:21:03 4 operating rooms.

11:21:07 5 A. Did include valid scientific evidence, yes.

11:21:11 6 Q. Okay. I mean from your opinion of the Bair
11:21:13 7 Hugger's use in operating rooms.

11:21:14 8 A. I think it was either in the 500 or 505
11:21:18 9 there was -- there was information.

11:21:19 10 Q. All right. Well let's --

11:21:20 11 Do you have your report with you?

11:21:22 12 A. Yeah. On a flash drive, not in hard copy.

11:21:25 13 Q. Okay. I'll give you a copy.

11:21:37 14 MR. BANKSTON: Counsel, do you have a copy
11:21:38 15 or do you need one as well?

11:21:41 16 MS. EATON: I have one.

11:21:41 17 MR. BANKSTON: Okay. There we go.

11:21:44 18 (Document handed to Ms. Eaton.)

11:21:45 19 MS. EATON: Thank you.

11:21:48 20 Q. Can you flip to page 90 for me, sir.

11:21:51 21 A. Okay.

11:21:51 22 Q. The opinion that I'm specifically directing
11:22:02 23 you to here, and you can review this page, but the
11:22:05 24 opinion I'm directing you to is the part that begins
11:22:07 25 with "The 510(k) submission for the Model 500..." Do

11:22:11 1 you see that statement?

11:22:11 2 A. Yes.

11:22:12 3 Q. Okay. And that statement reads that "The
11:22:14 4 model 510(k) submission for the Model 500" --

11:22:18 5 Excuse me. Let me rephrase that for the
11:22:20 6 record. This states that "The 510(k) submission for
11:22:22 7 the Model 500 included valid scientific evidence of
11:22:26 8 the Bair Hugger's use in operating rooms." That's
11:22:29 9 what your statement is.

11:22:30 10 A. That's what my statement is.

11:22:32 11 Q. Okay. Then there's a footnote; correct?

11:22:34 12 A. Yes.

11:22:34 13 Q. And a cite to a document?

11:22:36 14 A. Yes.

11:22:36 15 Q. Okay. That document citation reads
11:22:50 16 3MBH00047446.

11:22:51 17 A. Correct.

11:22:52 18 Q. Okay.

11:23:01 19 (Ulatowski Exhibit 3 was marked for
11:23:08 20 identification.)

11:23:08 21 MS. EATON: I'm sorry. We did not mark the
11:23:10 22 report as an exhibit?

11:23:11 23 MR. BANKSTON: Huh-uh.

11:23:16 24 MS. EATON: Okay.

11:23:16 25 BY MR. BANKSTON:

11:23:17 1 Q. All right, Mr. Ulatowski, this is the
11:23:18 2 document you cited for your opinion that there was
11:23:20 3 valid scientific evidence for the submission of the
11:23:24 4 model 500 for its use in operating rooms; correct?

11:23:27 5 A. This is the document I refer to.

11:23:29 6 Q. That is what you were using to support your
11:23:31 7 opinion in that report.

11:23:32 8 A. This is a document, yes. This is the
11:23:36 9 document I referred to, not --

11:23:37 10 Q. That was specifically --

11:23:39 11 A. It's not necessarily the only document that
11:23:41 12 may be relevant.

11:23:42 13 Q. Okay. We'll get to that in a second.

11:23:45 14 Let's talk about this document that you
11:23:46 15 cited in your report. There's a reason you cited this
11:23:50 16 document; right?

11:23:50 17 A. Sure.

11:23:51 18 Q. You were trying to convince us -- the --

11:23:53 19 Your report is -- is making the opinion that
11:23:57 20 there was, when the 500 was submitted and cleared by
11:24:01 21 the FDA, valid scientific evidence of its use in
11:24:03 22 operating rooms, and this document was cited to help
11:24:07 23 establish that.

11:24:09 24 A. Yes. And -- and what it refers to, yes.

11:24:11 25 Q. Okay. So let's talk a little bit about this

11:24:13 1 document. This document is dated July 10, 1990;

11:24:16 2 correct?

11:24:16 3 A. Yes.

11:24:17 4 Q. Okay. Is that before or after the clearance
11:24:20 5 of the Bair Hugger 500?

11:24:20 6 A. Well this would be before.

11:24:22 7 Q. Okay. This states that "Since its
11:24:27 8 introduction to the market approximately 20 months
11:24:30 9 ago, the Bair Hugger Convective Warming Therapy has
11:24:33 10 enjoyed a rapid acceptance by the Acute Care medical
11:24:38 11 community. In the first 20 months of use, over
11:24:41 12 400,000 hypothermic patients have been treated in Post
11:24:46 13 Anesthesia Care Unit (recovery room), Intensive Care,
11:24:49 14 operating room, emergency room and labor and delivery
11:24:52 15 suite."

11:24:53 16 Did I read that paragraph correctly?

11:24:54 17 A. Yes.

11:24:54 18 Q. Okay. That paragraph does not support the
11:24:57 19 idea that there's valid scientific evidence of its use
11:24:59 20 in the operating room; right? That's not the part of
11:25:03 21 the letter that's important.

11:25:03 22 A. Well I was also --

11:25:05 23 This embodies the references.

11:25:08 24 Q. What embodies the references? I'm sorry.

11:25:10 25 A. This -- this letter here.

11:25:11 1 Q. Okay. Sure. And I'm just going through it
11:25:13 2 piece by piece.

11:25:16 3 A. Yeah. Yeah.

11:25:16 4 Q. This particular paragraph, there's nothing
11:25:16 5 from that paragraph that you're using to support the
11:25:19 6 idea that there's valid scientific evidence.

11:25:21 7 A. Well it alludes to valid scientific
11:25:23 8 evidence.

11:25:24 9 Q. In what way does this paragraph allude to
11:25:27 10 valid scientific evidence?

11:25:28 11 A. Well first, understand what constitutes
11:25:31 12 valid scien -- scientific evidence, and it's -- it's
11:25:35 13 quite broad for medical devices and can include not
11:25:38 14 only the traditional controlled clinical studies, it
11:25:41 15 can include reports of significant human experience,
11:25:45 16 so statements like this could be implied to be valid
11:25:48 17 scientif -- scientific evidence.

11:25:51 18 Q. Scott Augustine writing to the FDA saying
11:25:53 19 I've sold a lot of my product and it's been used in
11:25:56 20 400,000 patients, that's a statement of safety to you,
11:25:58 21 that's valid scientific evidence of safety.

11:26:01 22 MS. EATON: Object to the form of the
11:26:02 23 question.

11:26:02 24 A. That's a statement of usage which then FDA
11:26:05 25 can begin to rely upon, using the other information

11:26:09 1 provided as well as the information they can bring to
11:26:12 2 bear.

11:26:12 3 Q. Okay. Let's talk about the next statement
11:26:14 4 which is, "Published clinical and laboratory evidence
11:26:17 5 has proven the Bair Hugger to be a very effective
11:26:20 6 active warming device (see enclosed Articles 1 to
11:26:26 7 15)." Is this the part of the letter that supports
11:26:28 8 valid scientific evidence?

11:26:30 9 A. Well those articles would be valid
11:26:32 10 scientific evidence.

11:26:33 11 Q. That's the --

11:26:34 12 I'm sorry, I didn't mean to interrupt.

11:26:35 13 A. No. To the degree that they refer to OR use
11:26:37 14 or -- or other uses, yes, they're valid scientific
11:26:41 15 evidence.

11:26:41 16 Q. Okay. Is it your --

11:26:43 17 Have you reviewed those articles?

11:26:44 18 A. Not in the last few days, no.

11:26:47 19 Q. Okay. But you believe you have reviewed
11:26:48 20 articles 1 through 15 as listed in this letter.

11:26:51 21 A. I believe so, yes.

11:26:51 22 Q. Okay. Can you tell me any article that
11:26:54 23 would have been included in this enclosure that in any
11:26:57 24 way is valid scientific evidence of the Bair Hugger's
11:27:00 25 safety in ORs?

11:27:01 1 A. I'd have to look at those articles. I think

11:27:03 2 either in this 5 -- I may be --

11:27:06 3 As I recollect, there was one paper

11:27:12 4 discussing OR use of the Bair Hugger.

11:27:15 5 Q. Okay. Do you have any idea what that is?

11:27:18 6 A. No. I don't recall specifically.

11:27:19 7 Q. Is that the Hall poster?

11:27:21 8 A. I don't think so, but --

11:27:22 9 Q. Okay.

11:27:23 10 A. Yeah.

11:27:23 11 Q. Is that Zink or Iaizzo?

11:27:26 12 A. I -- I --

11:27:27 13 As I said, I don't recall.

11:27:28 14 Q. Okay. You have your Exhibit B with you here
11:27:30 15 today that you rely on; right?

11:27:32 16 A. Yes.

17 Q. List all the studies you've relied on.

18 A. Yes.

19 Q. In looking at that list, can you find it for
11:27:35 20 me?

11:27:35 21 A. Well we'd have to look at this exhibit, one
11:27:38 22 through 15.

11:27:39 23 Q. Actually, let's just go out -- outside the

11:27:41 24 exhibit right now. Let's say even if it wasn't found

11:27:44 25 in this letter, okay, is there any study that you know

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11:27:45 1 of that existed in July of 1990 which is -- is valid
11:27:52 2 scientific evidence of the safety of the Bair Hugger
11:27:54 3 in an operating room?

11:27:56 4 A. Well I'd have to refer to these exhibits for
11:27:58 5 starters.

11:27:58 6 Q. What exhibits?

11:28:00 7 A. One through 15.

11:28:01 8 Q. I actually just said don't --

11:28:03 9 Forget about the letter.

11:28:04 10 A. Well --

11:28:05 11 Q. Let's not talk about the letter. Put it --
11:28:06 12 put it a little over to the side so we don't think
11:28:09 13 about it.

11:28:09 14 I just want to know from your report and the
11:28:12 15 materials you cited in your report -- you have a long
11:28:13 16 list of literature and that's what I'm here to talk to
11:28:16 17 you about today -- I want to know anywhere in that
11:28:20 18 literature is there a study that existed before 1990,
11:28:22 19 at the time the Bair Hugger was approved, that gave
11:28:23 20 valid scientific evidence of its safety in an
11:28:26 21 operating room?

11:28:26 22 A. I'd have to look at that again.

11:28:28 23 Q. Okay. But it is your opinion, you are
11:28:31 24 giving the opinion that the 510(k) process was proper
11:28:37 25 and that clearance was properly granted because there

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11:28:41 1 was valid scientific evidence as of this date of the
11:28:44 2 Bair Hugger's safety in an operating room.

11:28:45 3 A. Yes.

11:28:45 4 MS. EATON: Object to the form of the
11:28:47 5 question.

11:28:48 6 Q. Okay. You just can't tell me what that
11:28:49 7 evidence is right now.

11:28:50 8 A. Well you're putting me at a disadvantage.

11:28:53 9 Q. I --

11:28:53 10 In what way, sir? You -- you knew you were
11:28:56 11 coming here to give a deposition today; right? I
11:28:58 12 didn't catch you off guard; did I?

11:28:59 13 A. Yeah. I don't -- I don't typically try to
11:29:02 14 memorize clinical studies, authors and whatnot. I
11:29:05 15 know attorneys in deposition try to quiz people on --
11:29:08 16 in regard to that: "Well what's the name? What's the
11:29:10 17 date?" You know, really, come on.

11:29:13 18 Q. Do you think it's a gotcha question, sir,
11:29:16 19 for me to ask you, these 2,000 plaintiffs, can you
11:29:19 20 name one piece of literature that supports your
11:29:21 21 opinions that the FDA properly granted clearance
11:29:24 22 because the Bair Hugger is safe?

11:29:27 23 A. Well allow me --

11:29:27 24 Q. Is it?

11:29:27 25 A. Allow me to evaluate what -- what this

11:29:29 1 document is and I will tell you --

11:29:31 2 Q. I'm -- I'm not --

11:29:33 3 Again, sir, I'm not --

4 A. Well --

11:29:35 5 Q. -- talking about the document. I'm -- I'm

11:29:35 6 asking you: You gave opinions in this case, you're

11:29:36 7 being paid handsomely to give those opinions, and you

11:29:40 8 have shown up to this room to say that the Bair

11:29:44 9 Hugger's clearance was properly granted. I mean that

11:29:46 10 is the bulk of what you are here to say. And I'm not

11:29:49 11 asking you about some sort of ancillary issue or study

11:29:52 12 dug up from the bottom of our case files. What I want

11:29:56 13 to know is, if you're going to give this jury the

11:29:58 14 opinion that clearance was properly granted because

11:30:00 15 there was valid evidence of the Bair Hugger's safety

11:30:02 16 in an operating room at the time of clearance, do you

11:30:05 17 think that you could be able to tell me at all what

11:30:07 18 that evidence is?

11:30:08 19 MS. EATON: Object to the form of the

11:30:11 20 question.

11:30:13 21 A. My answer isn't going to change.

11:30:15 22 Q. Okay. Is that something that, if you were

11:30:21 23 to take time to look at the exhibit list of the things

11:30:25 24 you've reviewed, the studies that you have reviewed

11:30:28 25 and are relying on for your opinions, you could

11:30:30 1 identify that for me? Right?

11:30:33 2 A. Well I imagine as we get to -- to trial I'll
11:30:36 3 be responsive to that.

11:30:40 4 Q. I'm sure we'll ask questions at trial, but
11:30:44 5 sir, I'm here today to find out your opinions. I get
11:30:45 6 one shot to find out before trial what you're going to
11:30:48 7 say, and this is that day. So what I'm asking you:
11:30:50 8 If you were perform -- if you were afforded the
11:30:52 9 opportunity and the time to look at that list, knowing
11:30:55 10 the materials like you do and the opinions you have,
11:30:57 11 you could identify for me what you're talking about;
11:31:00 12 right?

11:31:00 13 A. I -- I think it's a rare case when -- when I
11:31:04 14 can, in deposition, provide verse -- chapter and verse
11:31:10 15 of clinical articles and -- and the substance of them.
11:31:12 16 I -- I always refer back to the articles, you know, de
11:31:20 17 novo, and look at the information. So --

11:31:21 18 Q. Okay.

11:31:22 19 A. You know, that's just the way it is.

20 MS. EATON: Repeatedly you --

21 Q. My question --

11:31:24 22 A. That's my style, and if you don't like it,
11:31:26 23 well I guess that's too bad.

11:31:27 24 MS. EATON: And to be clear, I would like to
11:31:29 25 say in fairness what Mr. Ulatowski did is cite a

11:31:33 1 document, and what he's asked you to do is provide him
11:31:35 2 the article cited within the document so that he could
11:31:36 3 review that.

11:31:36 4 MR. BANKSTON: Okay. First of all, that's
11:31:38 5 not an objection. Second of all, I've already said
11:31:41 6 three times put that document over there, I don't want
11:31:43 7 to talk about that document any more.

11:31:45 8 Q. What we are talking about is what you came
11:31:47 9 to in your report, which is a statement that there is
11:31:48 10 valid scientific evidence of the Bair Hugger's use in
11:31:51 11 operating rooms and that that evidence existed at the
11:31:55 12 time of the Bair Hugger's clearance, and what I think
11:31:57 13 I'm understanding from you is that when I am here
11:32:00 14 today to ask you what evidence that is, what evidence
11:32:03 15 you're relying on to make that opinion, you are
11:32:05 16 telling me today in deposition you will not be able to
11:32:07 17 give me that answer.

11:32:08 18 A. I'm not prepared to give you that answer --

11:32:10 19 Q. Okay.

11:32:11 20 A. -- today.

11:32:11 21 Q. Thank you, sir.

11:32:12 22 A. Not to say it does not exist.

11:32:14 23 Q. Sure. Just not going to disclose that today
11:32:17 24 in the deposition that we are here to talk about.

11:32:20 25 A. Right.

11:32:21 1 Q. Okay.

11:32:30 2 MS. EATON: Object to the form of the
11:32:32 3 question.

11:32:32 4 Q. You also have the opinion that the expansion
11:32:33 5 of clinical settings for the use of the Bair Hugger is
11:32:37 6 legitimately encompassed by Bair Hugger's intended
11:32:39 7 use.

11:32:40 8 A. Yes.

11:32:40 9 Q. Okay. That means that 3M can put it into an
11:32:44 10 operating room with no controls over its intended use;
11:32:50 11 correct?

11:32:50 12 A. No. That's a different question.

11:32:51 13 Q. Okay. Well that's what I'm asking. Are you
11:32:54 14 saying that if 3M changes its intended use or --

11:33:00 15 This is going to be kind of a complicated
11:33:02 16 question because I think isn't your opinion that the
11:33:04 17 intended use has never changed?

11:33:04 18 A. It's never changed.

11:33:05 19 Q. So if it goes in an OR or not, that's not a
11:33:08 20 change of intended use to you.

11:33:09 21 A. Correct.

11:33:09 22 Q. Okay. And that's not a change of
11:33:11 23 indications for use.

11:33:14 24 A. It -- it -- it may be relative to
11:33:18 25 indications for use, but it's not a change in intended

11:33:21 1 use.

11:33:22 2 Q. Okay. Are you aware that the model 200
11:33:24 3 specifically said "Caution: This machine is not
11:33:26 4 intended for use in the operating room?"

11:33:32 5 A. Well that's fine, but that's not the
11:33:34 6 intended use. The functional purpose is to heat a
11:33:38 7 patient.

11:33:38 8 Q. Okay.

11:33:39 9 A. That's --

11:33:40 10 Q. So --

11:33:40 11 A. So that -- that is another form of statement
11:33:44 12 that has a particular application.

11:33:47 13 Q. I get it. Okay. So when they say -- the
11:33:49 14 company says on the model 200, "Caution: This machine
11:33:52 15 is not intended for use in an operating room," that is
11:33:55 16 not relevant to what its intended use is.

11:33:59 17 A. Not in the broad sense of the functional
11:34:01 18 purposes of the device, which is to heat patients.

11:34:03 19 Q. Okay. And that's the regulatory part,
11:34:05 20 right, that that's --

11:34:06 21 A. Correct.

11:34:07 22 Q. -- most important when we're talking about
11:34:08 23 regulation; right?

11:34:09 24 A. Well, that's what we're talking about,
11:34:13 25 510(k) clearance --

11:34:13 1 Q. Right.

11:34:13 2 A. -- plus --

11:34:13 3 Q. But in other words, what I meant is this
11:34:15 4 statement from the company, the warning on the device,
11:34:20 5 that -- when they're talking about intended use,
11:34:22 6 you're saying they're not using it in the way --
11:34:24 7 "using" meaning using the term "intended use" -- in
11:34:24 8 the way the regulation uses it.

11:34:26 9 MS. EATON: Object to the form of the
11:34:27 10 question.

11:34:28 11 A. I -- I think it's relevant in regard to an
11:34:30 12 indication, an environment of use. Does it affect the
11:34:35 13 intended use overall? No. No.

11:34:35 14 Q. Well I -- I guess what I'm saying is just
11:34:37 15 because they say on the model 200, they say this
11:34:40 16 machine is not intended for use in the operating room,
11:34:43 17 according to you the regulatory definition of
11:34:46 18 "intended use" does encompass its use in the operating
11:34:49 19 room.

11:34:51 20 A. Correct. It's -- it's because there --
11:34:52 21 you --

11:34:53 22 You need to understand from a regulatory
11:34:55 23 point of view, and Dr. David as well, that -- that
11:35:03 24 "intended use" has a particular meaning in a
11:35:05 25 regulatory environment in terms of substantial

11:35:08 1 equivalence.

11:35:11 2 Q. Correct. So --

11:35:11 3 A. And -- and there's guidance documents on
11:35:12 4 that, there's explanations of that, and -- and FDA can
11:35:16 5 apply that broadly or -- or, when necessary, narrowly.
11:35:20 6 In this case, as I've interpreted it, the devices over
11:35:25 7 time, and as the classification of the product
11:35:28 8 identify their products, the classification says these
11:35:32 9 are products intended to heat patients.

11:35:32 10 Q. Okay.

11:35:35 11 A. It doesn't say in an OR, doesn't say at
11:35:37 12 home, doesn't say anywhere. It says the intended --

11:35:40 13 Q. Where does it say that? I'm sorry.

11:35:41 14 A. In the classification regulation for this --

15 Q. Got you.

11:35:43 16 A. -- type of device.

11:35:44 17 Q. Okay. So when 3M says "Caution: This
11:35:48 18 device is not intended for use in the OR," they are
11:35:49 19 not using the "intended use" in the same way you would
11:35:53 20 use it in the FDA for regulatory purposes.

11:35:56 21 A. Yeah. I don't think so. I think it's a
11:35:57 22 restricted application, but it doesn't really change
11:36:00 23 the -- the fundamental intended use.

11:36:05 24 Q. So when we're --

11:36:05 25 MS. EATON: Object to the form of the

11:36:05 1 question. That misrepresented the document.

11:36:05 2 MR. BANKSTON: Okay.

11:36:06 3 Q. When we're talking about intended use and
11:36:09 4 indications for use, okay, and those two things, --

11:36:11 5 A. Yes.

11:36:12 6 Q. -- and they were whatever they were for the
11:36:14 7 Bair Hugger 200, --

11:36:15 8 A. Right.

11:36:15 9 Q. -- and then the Bair Hugger 500 starts
11:36:18 10 getting used in operating rooms, --

11:36:19 11 A. Correct.

11:36:20 12 Q. -- it's your testimony that neither the IFU
11:36:22 13 nor the intended use has changed; correct?

11:36:24 14 MS. EATON: Object to the form of the
11:36:25 15 question.

11:36:27 16 A. The intended use has not changed.

11:36:28 17 Q. So its -- its sudden deployment into the
11:36:30 18 operating room with a new device, that really has no
11:36:33 19 regulatory impact or consequence.

11:36:35 20 MS. EATON: Object to the form of the
11:36:37 21 question.

11:36:37 22 A. It may. It may.

11:36:38 23 And you said "sudden." I'm not sure whether
11:36:41 24 it's sudden or became, you know, the standard for not
11:36:45 25 just Bair Hugger but for all heating devices, the

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11:36:48 1 standard of care as it evolved. But the point of the

11:36:52 2 fact is that device usage does evolve. It --

11:36:57 3 There may be impact on that evolutionary

11:37:00 4 usage, and in fact FDA identified -- they -- they --

11:37:05 5 they -- they put a stop point, so to speak, by

11:37:09 6 identifying home use as a potential problem --

11:37:13 7 Q. Okay.

11:37:13 8 A. -- in the use of the product.

11:37:16 9 Q. There are certain times and during the

11:37:18 10 510(k) clearance process --

11:37:20 11 Let me -- let me back up a little bit.

11:37:22 12 You've seen, I take it, on decision-making documents

11:37:24 13 for 510(k) a little flowchart, checklist?

11:37:26 14 A. Sure. Sure.

11:37:27 15 Q. And -- and sometimes it will say things like

11:37:29 16 are there any differences in the device, and yes/no;

11:37:32 17 right?

11:37:32 18 A. Correct.

11:37:32 19 Q. And then like if that one is answered yes,

11:37:35 20 the next question might be does it raise any new

11:37:37 21 safety questions or new effectiveness questions.

11:37:40 22 A. Correct.

11:37:41 23 Q. Right. So in other words, there are certain

11:37:42 24 times in the 510(k) process where the FDA learns of a

11:37:45 25 piece of information, and because of that new piece of

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11:37:49 1 information it must make an assessment or at least ask

11:37:52 2 the question does that raise new questions of safety.

11:37:55 3 A. Correct. Whenever -- whenever --

11:37:58 4 Now we've gone beyond intended use.

11:38:00 5 Q. Right. Exactly.

11:38:01 6 A. We've now gone to different technological

11:38:04 7 characteristics.

11:38:05 8 Q. Right.

11:38:05 9 A. And if there are any differences, the first

11:38:07 10 issue is, well, do these differences raise new types

11:38:10 11 of questions, --

11:38:10 12 Q. Right. And that's the point --

11:38:12 13 A. -- which gen -- generally is not -- is a

11:38:12 14 null for this kind of product.

11:38:13 15 Q. I got you. Okay.

16 MS. EATON: Let me just pause here and ask
17 if you two would both -- essentially you keep jumping
18 in on him when he's still talking and I ask you to
19 please stop that.

20 MR. BANKSTON: Yeah, I know. I keeping
21 thinking this over. Exactly. No, I get it.

22 Q. When -- when --

11:38:27 23 One of the things you talked about was

11:38:30 24 different technological characteristics. If that's

11:38:32 25 the case, then -- then that question has to be asked.

11:38:34 1 That's one of the situations; right?

11:38:35 2 A. It -- it always has to be asked.

11:38:37 3 Q. No. For instance, if what I'm asking is --
11:38:41 4 is if their conclusion is made that there are no
11:38:41 5 technological differences, then you obviously don't
11:38:43 6 have to ask the question do the differences make a
11:38:46 7 difference in safety and effectiveness because there's
11:38:48 8 no differences; right?

11:38:49 9 A. Right. But that's rare.

11:38:51 10 Q. Okay. So --

11:38:52 11 But you occasionally do have a product that
11:38:55 12 has no -- it's a new product that has no changes in --
11:38:57 13 in -- in technological characteristics.

11:38:59 14 A. Right.

11:39:00 15 Q. Usually that's not going to require a brand
11:39:03 16 new 5(k) -- 510(k).

11:39:07 17 A. It may. For example, if -- if a device is
11:39:07 18 being used in an entirely different clinical purpose,
11:39:15 19 not OR versus non-OR but -- but for an entirely new
11:39:19 20 disease condition, gone from neurological to
11:39:23 21 cardiovascular, some disease, but the device is the
11:39:27 22 same device, well there you don't -- you have the same
11:39:28 23 technology, you have the same device, but now you've
11:39:31 24 changed its -- it's significantly changed its
11:39:35 25 condition of use.

11:39:37 1 Q. I'm glad that --

11:39:37 2 Interesting, because that's exactly where I
11:39:40 3 was going to be going, is that there are other things
11:39:42 4 with the device that can change besides technological
11:39:45 5 characteristics that would require the FDA to ask that
11:39:48 6 question again, is there a possible effect on the
11:39:49 7 safety, and one of those things that could change is
11:39:52 8 the indications for use.

11:39:53 9 A. Right. It may --

11:39:54 10 But those are typically very significant
11:39:56 11 changes.

11:39:56 12 Q. Sure. So, for instance, say you had a
11:39:59 13 device and it had a -- a very significant change in
11:40:02 14 the indications for use. One day it's being used to
11:40:05 15 treat bunions, the next day it's in brain surgery.
11:40:09 16 Right? If you have that kind of significant change,
11:40:13 17 there's going to need to be the question asked does it
11:40:13 18 raise any safety or effectiveness questions.

11:40:13 19 A. Correct.

11:40:14 20 Q. If the IFUs are not changed, there's no
11:40:17 21 change in the IFUs, you don't have to ask if there's
11:40:21 22 any changes in safety and effectiveness for the IFUs
11:40:23 23 because those IFUs haven't changed.

11:40:25 24 A. Correct.

11:40:25 25 Q. You might have to ask it for other things

11:40:28 1 like technological characteristics, but not for the
11:40:31 2 IFUs.

11:40:31 3 A. Correct.

11:40:31 4 Q. Okay. What about intended use? If intended
11:40:33 5 use changes, do you have to then do the same flowchart
11:40:36 6 process and ask if it raises new questions?

11:40:39 7 A. No. If there's a new intended use,
11:40:41 8 you're -- you're typically dead in the water at that
11:40:43 9 point in time.

11:40:43 10 Q. Got you. Okay. So if -- if --

11:40:45 11 Stay with the Bair Hugger for instance. One
11:40:46 12 of the things I think you'll agree with me on is we
11:40:49 13 had talked about its use between the 200 and the 500
11:40:53 14 and the 500 series being -- starting to be used in the
11:40:55 15 ORs.

11:40:55 16 A. Yes.

11:40:55 17 Q. And that's not a change in the indications
11:40:58 18 for use.

11:40:58 19 A. No, that's not -- that's not a significant
11:41:01 20 change as FDA has evaluated devices used in hospitals.

11:41:04 21 Q. Sure. And the Bair Hugger 200 to 500,
11:41:06 22 there's not a significant different technology being
11:41:09 23 used; correct?

11:41:09 24 A. Fundamentally, no.

11:41:10 25 Q. Okay. So in neither of these cases with the

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11:41:13 1 200 to 500 under FDA regulations for the indications
11:41:18 2 for use, in other words, it -- it being used in an OR
11:41:20 3 didn't change that, so when the 200 goes to the 500 --

11:41:26 4 Let me -- let me rephrase this because I'm
11:41:27 5 really trying to understand. If -- if -- if the 200
11:41:32 6 is being used not in ORs and the 500 is being used in
11:41:36 7 ORs but there's no change in IFUs and there's no
11:41:39 8 change in technology, there's no need to ask if that
11:41:42 9 use in OR raises new questions of safety or
11:41:44 10 effectiveness; right?

11:41:47 11 A. If the intended use is the same, looking at,
11:41:50 12 you know, what Dr. Augustine said particularly here,
11:41:55 13 and understanding FDA's viewpoint on the flexibility
11:41:58 14 in regard to in-hospital product usage, that, you
11:42:03 15 know, they would look at this, they'd evaluate it as
11:42:07 16 they are required to do, but then they'd move on to
11:42:09 17 the technology and any test results that were
11:42:12 18 obtained --

11:42:13 19 Q. Okay.

11:42:13 20 A. -- with -- with the 500.

11:42:14 21 Q. I'm not sure I understand the answer there
11:42:17 22 about whether, if the Bair Hugger -- new model of Bair
11:42:21 23 Hugger is going to be used in the OR --

11:42:24 24 A. Uh-huh?

11:42:24 25 Q. -- but that doesn't constitute a change in

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11:42:25 1 the indications for use, that means you don't have to
11:42:27 2 do -- at the FDA you don't have to ask if that
11:42:31 3 raises -- the use the in the OR raises new questions
11:42:36 4 of safety or effectiveness because the IFUs are the
11:42:38 5 same. Right?

11:42:39 6 A. Well there is a -- there is a different
11:42:40 7 environment in change. That would be assessed. But
11:42:43 8 did it change the intended use? No, it didn't change
11:42:46 9 the intended use of the product.

10 Q. When you mean --

11:42:48 11 A. It's still warming, the product.

11:42:49 12 Q. When you mean it would be the environment of
11:42:51 13 use --

11:42:51 14 Is that what you said?

11:42:52 15 A. Environment of use.

11:42:52 16 Q. Okay. The environment of use would be
11:42:54 17 assessed; is that --

11:42:56 18 A. It would be assessed to what degree there's
11:42:58 19 any difference or extraordinary change in use of this
11:43:01 20 type of product. You know, you have to understand
11:43:04 21 there's --

11:43:06 22 The Bair Hugger is but one heating type of
11:43:08 23 device. There were other predicate heating devices of
11:43:11 24 course. There's evolution of -- of use of the
11:43:16 25 on-the-market heating devices, there's FDA's knowledge

11:43:20 1 of evolutionary changes of the use of heating devices.
11:43:24 2 It -- it may not be particularly highly significant to
11:43:29 3 FDA, the evolution into the OR.

11:43:32 4 Q. I -- I -- I had thought that you had
11:43:34 5 testified that if IFUs change, there has to be a
11:43:38 6 safety -- you know, safety questions asked.

11:43:40 7 A. Right. If there's any --

11:43:41 8 Q. But -- hold on.

11:43:42 9 A. Any differences in the IFUs need to be
11:43:45 10 assessed.

11:43:45 11 Q. Right. But if there's differences in
11:43:48 12 intended use, the 510(k) does not require to ask if it
11:43:52 13 raises new questions of safety and effectiveness.

11:43:52 14 A. Ultimately FDA's decision, based upon its
11:43:55 15 comparison of labels, is there's no difference in
11:43:58 16 intended use.

11:44:00 17 Q. Correct. Okay. So if there is no
11:44:00 18 inten -- there's no difference in intended use, okay,
11:44:03 19 if the FDA concludes that there's no difference in
11:44:05 20 intended use, nothing further needs to be done
11:44:08 21 regarding the subject of intended use.

11:44:10 22 A. Correct.

11:44:12 23 Q. Do you agree with me?

11:44:12 24 A. Correct.

11:44:12 25 Q. Are you saying that if the FDA finds there

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11:44:14 1 is a substantially different intended use, the FDA
11:44:17 2 then must, under the regulations, ask if that change
11:44:20 3 in intended use raises new questions of safety and
11:44:22 4 effectiveness?

11:44:23 5 A. Well let me back up a little bit.

11:44:26 6 Q. Uh-huh.

11:44:26 7 A. FDA examines the differences. Whatever
11:44:30 8 differences exist, FDA will -- may, I'll say, consider
11:44:33 9 safety and effectiveness at that point in time, thus
11:44:38 10 rendering the decision ultimately it's a new intended
11:44:40 11 use or it's not a new intended use. My -- my
11:44:43 12 additional point is that the evolution of products
11:44:47 13 within the hospital and its -- their usage in and out
11:44:49 14 of ORs, I've seen that in other types of devices, it's
11:44:55 15 not been particularly a turning point on new intended
11:44:58 16 use.

11:44:58 17 Q. Okay. I want to make sure I'm not -- I
11:45:02 18 totally have this understood, so let's -- let's go
11:45:04 19 through the three different things we're talking about
11:45:06 20 here, which is, first, technological characteristics.
11:45:10 21 If character --

11:45:12 22 That's something that, if it changes, the
11:45:12 23 FDA regulations require that you ask if it raises new
11:45:15 24 questions of safety and effectiveness. Yes?

11:45:17 25 A. Say it again. Sorry.

11:45:18 1 Q. If there are technological differences
11:45:20 2 between the two products, --

11:45:21 3 A. Yes, yes.

11:45:21 4 Q. -- then if that exists, then the regulations
11:45:24 5 require the FDA to ask whether that raises new
11:45:27 6 questions of safety.

11:45:27 7 A. New types of safety questions, yes.

11:45:29 8 Q. Okay.

11:45:30 9 A. Or effectiveness questions.

11:45:31 10 Q. Second one was indications for use.

11:45:33 11 A. Right.

11:45:36 12 Q. If indications for use change, the FDA under
11:45:38 13 510(k) has to ask the question does it raise new
11:45:41 14 safety questions.

11:45:43 15 A. Right. FDA will examine the two labels,
11:45:48 16 here's the indications, here's the indications, is
11:45:48 17 there something significant here? If so, let's
11:45:53 18 analyze the safety and effectiveness impact. No
11:45:56 19 impact, same intended use.

11:45:57 20 Q. All right. I'm not terribly concerned about
11:46:00 21 the methodology at this point. What I really wanted
11:46:03 22 to know is if there is a change in intended use, the
11:46:07 23 regulations direct the reviewer to ask if there is a
11:46:09 24 difference in safety.

11:46:10 25 A. No. If there's a change in intended use --

11:46:12 1 Q. That's -- okay. Let me --

11:46:14 2 And you're right, I -- I messed up the word,
11:46:15 3 so let's go back.

11:46:17 4 A. The end result is you're not equivalent.

11:46:19 5 Q. Right. Let's go back and -- and --

11:46:20 6 A. If there's a change in indications for use,
11:46:23 7 it may or may not be equivalent.

11:46:24 8 Q. Got you. So --

11:46:26 9 In fact, that's what I did, is I said it
11:46:26 10 wrong.

11:46:26 11 So the second one we talked about was
11:46:28 12 indications for use.

11:46:29 13 A. Right.

11:46:29 14 Q. And if there is a different indication for
11:46:32 15 use on the labeling, that will trigger a question of
11:46:35 16 whether there is new safety questions.

11:46:37 17 A. Right. What's --

11:46:39 18 Q. Okay.

11:46:39 19 A. What's -- what's the indication? Is it in
11:46:41 20 this case warming of patients perioperatively,
11:46:45 21 preoperatively, postoperatively? You know, we're on a
11:46:49 22 continuum there of sorts.

11:46:50 23 Q. Hold on, hold on, let me make sure I
11:46:53 24 understand that. When you say indications for use and
11:46:56 25 you said whether you're warming a patient

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11:46:58 1 preoperatively, perioperatively or postoperatively, --

11:47:00 2 A. Right.

11:47:00 3 Q. -- so where you use the device, whether or

11:47:03 4 not it's in an OR, that's a part of the indications

5 for use.

11:47:06 6 A. Right. The usage environment, as I said.

11:47:07 7 Q. Okay. So --

11:47:08 8 But I thought I understood that from the 200

11:47:10 9 to the 500 series the indications for use didn't

11:47:13 10 change according to the FDA.

11:47:14 11 MS. EATON: Object to the form of the

11:47:15 12 question.

11:47:16 13 A. The intended use didn't change, the

11:47:17 14 environment of use changed.

11:47:19 15 Q. What I'm asking very specifically right now

11:47:20 16 is, because I thought I had this --

11:47:22 17 A. And maybe I mis -- misunderstood.

11:47:23 18 Q. Yeah. I think maybe we crossed at each

11:47:29 19 other at some point.

20 A. Yeah.

11:47:29 21 Q. But when you're saying when that 510(k) was

22 approved between the 200 and the 500 series, did the

11:47:32 23 FDA find the indications for use had changed or not?

11:47:36 24 A. As I -- as I would look at the 200 versus

11:47:40 25 the 500, I would see a difference in the -- in how

11:47:44 1 Augustine has described the 500 probably as compared
11:47:48 2 to the 200, so that would be observed by FDA, that
11:47:51 3 would be assessed for any impact on intended use.
11:47:56 4 But -- but again, I keep bringing this up --
11:47:58 5 Q. Hold on. I'm -- I'm really confused because
11:48:00 6 you just said "intended use."
11:48:01 7 MS. EATON: He was trying to finish his
11:48:04 8 answer.
11:48:04 9 Q. Yeah. Like I just want to make sure we're
11:48:05 10 not -- I just wanted to correct the record --
11 11 A. Okay.
11:48:07 12 Q. -- because I knew you were in the middle of
13 your answer and you said "intended use" --
14 A. Well let me back up.
15 Q. -- not "indications for use."
11:48:08 16 A. Let me back up.
11:48:08 17 MS. EATON: But I believe that's what he
11:48:09 18 meant, So can we let him finish his answer?
11:48:12 19 MR. BANKSTON: Yeah. Let's find out.
11:48:13 20 A. You got the 200 label, --
11:48:15 21 Q. Uh-huh.
11:48:15 22 A. -- you got the 500 label --
23 Q. Okay.
11:48:17 24 A. -- and statements by Augustine, --
11:48:18 25 Q. Okay.

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11:48:20 1 A. -- because all statements within the 510(k)
11:48:22 2 contribute to intended use.

11:48:23 3 Q. Sure. Okay.

11:48:25 4 A. Okay? Whether or not the label even says
11:48:30 5 it, which is -- which is an interesting quirk of the
11:48:32 6 regulations. But even Augustine saying it's in the OR
11:48:37 7 has a hook on intended use.

11:48:38 8 Q. Sure. Okay.

11:48:41 9 A. Okay?

11:48:41 10 MS. EATON: Can I ask you to please wait
11:48:42 11 until he finishes his answer.

11:48:43 12 MR. BANKSTON: Oh. I'm trying to just -- so
11:48:45 13 we can understand each other. I'm sorry.

11:48:46 14 MS. EATON: I understand that, but I would
11:48:48 15 ask you to please wait.

11:48:49 16 A. Here -- here's the progression.

11:48:50 17 Q. Okay. My --

11:48:51 18 Sir, I'm sorry. Whenever you --

11:48:51 19 A. Here's the progression.

20 Q. Okay.

21 A. You get the 200 label, you get the 500
11:48:52 22 label, you look at the label. Is there a difference?
11:48:58 23 Well yes, there's a difference. Does that difference
11:49:02 24 raise issues of safety and effectiveness? Yes/no.
11:49:05 25 Based on not what's just in the 510(k), but everything

11:49:08 1 the else that can be brought to bear.

11:49:09 2 Q. Okay.

11:49:10 3 A. And then the decision made new intended use
11:49:15 4 or not new intended use.

11:49:16 5 Q. Okay. Have you ever heard --

11:49:17 6 You've heard the term "indications
11:49:19 7 statement."

11:49:19 8 A. Right.

11:49:20 9 Q. Right. And that's indications for use. Is
11:49:23 10 that related --

11 11 A. Right.

11:49:23 12 Q. -- to that topic?

11:49:26 13 A. You typically see that a lot in -- in drugs
11:49:27 14 and certain devices. Devices are a little bit unusual
11:49:30 15 because sometimes you -- you won't see indications for
11:49:32 16 use, --

11:49:32 17 Q. Okay.

11:49:33 18 A. -- you'll see a functional use, which is
11:49:35 19 really equivalent to the intended use.

11:49:38 20 Q. And I think from what we were talking about
11:49:40 21 with his letter and things like that, really anything
11:49:44 22 inclusive in the 510(k), the totality of information
11:49:46 23 there is relevant to what the indications for use
11:49:50 24 indications statement is.

11:49:50 25 A. It can be, yes.

11:49:51 1 Q. Okay. And so again from this situation, the
11:49:55 2 indications for use, the indications statement between
11:49:58 3 these two devices has changed.

11:50:01 4 A. Well the use condition --
11:50:02 5 They haven't characterized it as
11:50:05 6 indications, but the environment of use I'll
11:50:08 7 characterize for -- for purposes of this deposition as
11:50:09 8 indications for use.

11:50:10 9 Q. Got you. Okay. So I -- and basically --
11:50:13 10 I know we don't have the documents in front
11:50:15 11 of us, and so part of what I'm --

12 A. Yes.

11:50:16 13 Q. -- trying to do is reconstruct what the
11:50:18 14 front-line reviewer would have done in approving the
11:50:20 15 500 series from the 200 series.

11:50:23 16 A. Sure.

11:50:23 17 Q. And in part of that checklist he would have
11:50:27 18 had to go, first of all, is the device even subject to
11:50:29 19 510(k), and you would have said yes, this device is a
11:50:32 20 510(k)-subject device.

11:50:33 21 A. Yes. Is there a valid predicate? Has that
11:50:35 22 been presented in the 510(k)?

11:50:36 23 Q. Well I mean even before he starts looking at
11:50:38 24 predicate, he has know whether this device is even
11:50:41 25 subject to the regulation; right? It might be subject

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11:50:44 1 to PMA. You have to figure out what kind of device it
2 is. That would be your first step --

11:50:52 3 A. Well in -- in a very --

11:50:52 4 THE REPORTER: Just a moment.

5 THE WITNESS: We're stepping on each other.

11:50:52 6 THE REPORTER: You are. One at a time,

11:50:54 7 please.

11:50:54 8 Q. Let's -- let's -- let's do it real simply in
11:50:55 9 little chunks from this doc.

11:50:56 10 A. I'll slow up as well. Right.

11:51:00 11 Q. How about this way? Is the product --

11:51:00 12 The first thing you have to determine is is
11:51:02 13 the product a device.

11:51:05 14 A. Yes, generally, in a -- in a very general
11:51:08 15 manner.

11:51:08 16 Q. Now devices can be subject to different FDA
11:51:11 17 regulations.

11:51:12 18 A. Correct.

11:51:12 19 Q. One of those regulations is 510(k).

11:51:15 20 A. Correct.

11:51:16 21 Q. One --

11:51:17 22 So then one of the next things you have to
11:51:18 23 determine, is the device subject to 510(k)?

11:51:22 24 A. Yes. You may --

11:51:24 25 That may be a front-end decision or will

11:51:26 1 have to remain as a back-end determination.

11:51:29 2 Q. Right. Okay. And then one of the next
11:51:32 3 things you might do when actually looking at the
11:51:34 4 product -- and I'm not sure what order you might do
11:51:38 5 this, so if this is out of order, you know, I know --
11:51:39 6 but one of the steps might be does the product have
11:51:41 7 the same indication statement.

11:51:44 8 A. Right.

11:51:45 9 Q. And in this case you would conclude, no, it
11:51:49 10 doesn't, and then that would trigger you to ask the
11:51:51 11 question does that new indication for use present any
11:51:55 12 safety questions.

11:51:57 13 A. Yes.

11:51:57 14 Q. That would be the proper way for a 510(k)
11:52:00 15 reviewer to go about looking at this product.

11:52:02 16 A. Yes.

11:52:02 17 Q. Okay.

11:52:08 18 MR. BANKSTON: Are we at --

11:52:09 19 I'm not sure if my time is off of Central or
11:52:12 20 not. Are we near --

21 Are we at noon? Is that where we're at, or
11:52:15 22 are we at 11:00?

11:52:15 23 (Discussion off the stenographic record.)

11:52:16 24 (Luncheon recess taken.)

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12:48:36 1 AFTERNOON SESSION

12:48:37 2 BY MR. BANKSTON:

12:48:39 3 Q. Mr. Ulatowski, before we broke, we kind of
12:48:41 4 broke in the middle of going through a step-by-step
12:48:45 5 process by which a reviewer reviews a 510(k), and I
12:48:50 6 kind of wanted to pick back up on that a process. We
12:48:53 7 had talked --

12:48:54 8 We had kind of gone down some steps and we
12:48:56 9 kind of got interrupted in the steps, so I want to go
12:48:59 10 through the steps we had talked about. We had talked
12:49:01 11 about the determination is the product a device, and
12:49:04 12 then is it subject to 510(k), and then does it have
12:49:07 13 the same indications statement and indications for
12:49:11 14 use, and we had talked about when that question is
12:49:14 15 answered it would be in the affirmative for the Bair
12:49:17 16 Hugger in terms of its change for indications for use,
12:49:20 17 and then we go on to the next question, which is does
12:49:22 18 it raise new questions of safety and effectiveness.
12:49:25 19 Do you remember that discussion?

12:49:26 20 A. Right. I'm not quite sure you got all the
12:49:30 21 steps in place, but --

12:49:31 22 Q. Sure.

12:49:32 23 A. Is -- is it a device for sure. Is it
12:49:36 24 subject to 510(k), well that -- that may be a, as I
12:49:39 25 said, a front-end or a back-end determination, meaning

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12:49:43 1 front end you can tell it's a 510(k) device because
12:49:47 2 it's -- it's classified by FDA, there's a regulation
12:49:50 3 on that type of device and it's for a Class II device
12:49:54 4 you submit a 510(k), for some devices you really don't
12:49:57 5 know where it's going to fall out, and so you have to
12:49:59 6 kind of wait and see what the decision is. So is it
12:50:03 7 5 -- 510(k)-eligible? Is there a legally marketed
12:50:08 8 predicate? Yes/no. If you don't have a predicate,
12:50:11 9 you're going nowhere. Does -- does it have the same
12:50:15 10 intended use is the next point, and in making that
12:50:18 11 decision, the labeling -- labeling's examined one
12:50:22 12 against the other, any claims in the 510(k), any
12:50:25 13 statements in the 510(k) may describe aspects of
12:50:28 14 intended use, so all that's examined, and a decision
12:50:33 15 rendered based on all that information what
12:50:37 16 differences may exist or what similarities there are.
12:50:41 17 If there are significant differences, what effect may
12:50:45 18 it have on safety and effectiveness, and FDA will
12:50:48 19 assess that to the degree necessary using whatever
12:50:51 20 information it -- it needs to bring to bear.

12:50:53 21 Decision made on intended use, is it the
12:50:56 22 same or different? If it's the same, you move to the
12:50:59 23 next step. If it's a different intended use,
12:51:02 24 you're -- you're not equivalent.

12:51:03 25 Q. Okay.

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12:51:03 1 A. And -- and there's alternative steps that
12:51:06 2 can be taken then with -- with a different kind of
12:51:09 3 submission. But then -- then you line up the devices.
12:51:12 4 Is the technology the same or different? If it's
12:51:15 5 different, then the issue is, well, those -- do those
12:51:18 6 differences raise new types of safety and
12:51:20 7 effectiveness questions? If the answer is no, then
12:51:24 8 you move on to any performance data that's been
12:51:28 9 submitted or necessary as required by FDA, and then
12:51:32 10 that's assessed and then a final determination made on
12:51:35 11 equivalence.

12:51:36 12 Q. Okay. And we had started talking about how
12:51:39 13 those decisions would have been made with respect to
12:51:41 14 the Bair Hugger, and we hadn't quite gotten to some of
12:51:45 15 that later stuff you had been talking about, hopefully
12:51:47 16 we'll get to talk about it, different ways that
12:51:49 17 decisions were made. But with respect to the stuff
12:51:52 18 that we had just -- to pick up from where we were at
12:51:55 19 break, if the -- the proper way, the -- how this would
12:51:59 20 have been --

12:51:59 21 Let me back up. I understand you haven't --
12:52:01 22 you don't have access to the 510(k) decision-making
12:52:04 23 documents so you can't say this with absolute
12:52:06 24 certainty.

12:52:07 25 A. Right. Yes. So how I approach it is how --

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12:52:09 1 how would I have evaluated it based on what I see in
12:52:12 2 this 510(k).

12:52:12 3 Q. Yeah, absolutely. And so what we had talked
12:52:15 4 about was one of those -- one of those first questions
12:52:17 5 being about the indications statement or the
12:52:20 6 indications for use and that the reviewer would have
12:52:22 7 concluded that the Bair Hugger had a different
12:52:24 8 indications for use or different indications and then
12:52:27 9 would have then answered the question do those
12:52:31 10 questions -- do those new indications pose any new
12:52:34 11 questions of safety or effectiveness.

12:52:35 12 A. That's -- that's one of the possible
12:52:37 13 alternatives, or -- or the evaluator was com --
12:52:41 14 comfortable enough consolidating all hospital use into
12:52:46 15 one use condition.

12:52:46 16 Q. Sure.

12:52:47 17 A. So I mean there's alternatives that may have
12:52:48 18 occurred.

12:52:49 19 Q. Absolutely. Okay.

12:52:51 20 So with respect to the indications for like
12:52:53 21 hospital use or whatever the indications are, this
12:52:56 22 reviewer has -- the -- the fact that the 510(k)
12:53:00 23 does -- has gone, as you said, means that there was at
12:53:02 24 some point somebody at the FDA who looked at the
12:53:05 25 indications and then asked the question, and answered

12:53:07 1 it, does this raise new questions of safety or
12:53:10 2 effectiveness.

12:53:11 3 A. No, I -- I think -- I think you would have
12:53:17 4 to deal with that because in Augustine's setup
12:53:21 5 correspondence in comparison to the 200 labeling
12:53:24 6 there's enough difference there to evoke a response to
12:53:27 7 evaluate that sort of question.

12:53:28 8 Q. Got you. Okay.

12:53:29 9 A. So --

12:53:30 10 Q. So like --

12:53:32 11 No. I'm sorry.

12:53:32 12 A. So it's an issue as to degree of evaluation,
12:53:37 13 what's the expertise of the evaluator, what
12:53:39 14 information could she -- he or she bring to bear to
12:53:43 15 render a decision that, okay, I see a difference.
12:53:46 16 It's not a big deal. Same intended use.

12:53:49 17 Q. Okay. And for instance, we had talked about
12:53:51 18 Ulatowski Exhibit 3 there in front of you, the letter,
12:53:54 19 that sometimes other things that are given to the FDA
12:53:57 20 including commu -- communications from the
12:53:59 21 manufacturer can help inform intended use and
12:54:03 22 indications for use and an indications statement.

12:54:09 23 A. Yes, from the manufacturer or from any other
12:54:09 24 source.

12:54:09 25 Q. Okay. So this -- this reviewer had that

12:54:14 1 kind of information. I mean while -- while you
12:54:16 2 haven't seen the document for the actual decision-
12:54:18 3 making, you have seen these kind of documents to know
12:54:20 4 that the -- the reviewer had this kind of information
12:54:23 5 or the FDA had it at its disposal.

12:54:25 6 A. Yes.

12:54:26 7 Q. Okay. And so it --

12:54:29 8 Therefore, all of this that we've been
12:54:30 9 talking about, would you agree with me that this is
12:54:32 10 part of your support for your opinion that there was a
12:54:35 11 determination of safety and effectiveness for the
12:54:38 12 change in the indications of use for the Bair Hugger?

12:54:41 13 A. There was -- would have been an assessment
12:54:45 14 to one degree or another of the differences, including
12:54:49 15 differences and their impact on safety and
12:54:51 16 effectiveness.

12:54:51 17 Q. Okay.

12:54:52 18 A. Then moving on to the final decision -- the
12:54:55 19 decision, which is, is it the same intended use or
12:54:56 20 isn't it?

12:54:57 21 Q. Got you. Okay. So if we're following this
12:54:59 22 in a step-by-step process, like a flowchart process,
12:55:02 23 we -- one of the questions we'd be posed then was are
12:55:06 24 there different indications for use, and that question
12:55:08 25 would be answered yes, and then the following question

12:55:10 1 that would have to be answered is do those differences
12:55:13 2 pose any new questions of safety and effectiveness,
12:55:15 3 and the answer to that would be no; correct?

12:55:18 4 A. Well I think we're saying are the
12:55:22 5 indications different. Well I think there's different
12:55:24 6 wording, but within FDA's evaluation of devices, FDA
12:55:29 7 may be more allowing, if I can use that word, in
12:55:37 8 regard to differences in words or conditions than you
12:55:42 9 might think. For example, I said is this still used
12:55:47 10 in hospital? Yes/no. Is this outside of hospital
12:55:50 11 use? So it depends to what degree and level the FDA
12:55:54 12 evaluator considered those factors.

12:55:56 13 Q. Okay. Well let's talk about with this
12:55:58 14 device, the Bair Hugger, moving from the 200 to the
12:56:01 15 500. So the 500 was approved, and from what I'm
12:56:05 16 understanding from you, the FDA understood that there
12:56:08 17 was a change in indications for use but concluded that
12:56:11 18 those changes did not affect health and safety
12:56:15 19 questions.

12:56:16 20 MS. EATON: Object to the form of the
12:56:16 21 question.

12:56:17 22 A. I think that's the case.

12:56:18 23 Q. Okay.

12:56:35 24 (Ulatowski Exhibit 4 was marked for
12:56:37 25 identification.)

12:56:37 1 BY MR. BANKSTON:

12:56:38 2 Q. All right, sir, I've handed you what has
12:56:40 3 been marked as Ulatowski Exhibit 4. You've seen one
12:56:43 4 of these documents -- type of documents before in your
12:56:46 5 career, correct, a "'SUBSTANTIAL EQUIVALENCE' DECISION
12:56:51 6 MAKING DOCUMENTATION?"

12:56:51 7 A. Yes.

12:56:51 8 Q. Okay. At the bottom of this document there
12:56:53 9 is Bates numbers; correct?

12:56:54 10 A. Yes.

12:56:56 11 Q. Okay. So this is a document from this
12:56:58 12 litigation. You understand that?

12:56:59 13 A. Yes.

12:57:00 14 Q. Okay. This is not a document you have
12:57:02 15 reviewed.

12:57:03 16 A. No, I don't think I've seen this.

12:57:05 17 Q. Okay. And this is -- and --

12:57:05 18 And when we talk about decision-making
12:57:07 19 documentation on the 500, that was the -- the universe
12:57:10 20 of documents you had indicated before you did not have
12:57:13 21 available to you; correct?

12:57:13 22 A. This is a type of document, yes.

12:57:16 23 Q. Okay. And this document has a flowchart
12:57:18 24 like we've been talking about; correct?

12:57:19 25 A. It should have a flowchart, if I can turn to

12:57:22 1 the back.

12:57:22 2 Q. Well what I'm actually describing --

12:57:25 3 A. Oh. Well, okay.

12:57:25 4 Q. -- is the front page.

12:57:26 5 A. Yeah. But usually there was a flowchart
12:57:29 6 also attached to it.

12:57:29 7 Q. Okay. And I guess maybe a better way to
12:57:31 8 describe this would be a series of yes/no questions
12:57:34 9 and then with flowchart instructions off to the side;
12:57:37 10 correct?

12:57:37 11 A. Yes. Because there was a -- like I said, a
12:57:40 12 flowchart, that this described the flowchart.

12:57:42 13 Q. Okay. So --

12:57:43 14 And this reviewer, Glenn Bird --

12:57:45 15 You're familiar with Mr. Bird?

12:57:47 16 A. Yes, I know Glenn.

12:57:48 17 Q. Okay. And just as you see, the trade name
12:57:50 18 would be the Model 250 and 500; correct?

12:57:53 19 A. Yes. Well it lines up with that letter.

12:57:57 20 Q. Correct.

12:57:58 21 And then you'll also see that the product to
12:58:00 22 which it's compared is the Bair Hugger model 200;
12:58:03 23 correct?

12:58:03 24 A. Yeah. I'm looking at this.

12:58:06 25 Yes.

12:58:06 1 Q. Okay. So let's go down the checklist.

12:58:09 2 A. Okay.

12:58:09 3 Q. This reviewer --

12:58:11 4 A. Okay.

12:58:11 5 Q. -- on number one said the product is a

12:58:13 6 device.

12:58:15 7 A. Yes.

12:58:15 8 Q. Yes. Okay. And number two is he said it

12:58:19 9 was subject to 510(k) and said yes.

12:58:22 10 A. Correct.

12:58:22 11 Q. Okay. The next one is he says it has the

12:58:25 12 same indications statement; correct?

12:58:26 13 A. Yes.

12:58:27 14 Q. Okay. So that's a bit contrary to what

12:58:29 15 we've just been talking about; right?

12:58:30 16 A. No, not necessarily, because I said the

12:58:32 17 particular evaluator may have a -- a broader -- I

12:58:36 18 forget what term I used -- a more generous maybe I

12:58:40 19 said -- a broader interpretation of indication for

12:58:41 20 use.

12:58:41 21 Q. Do you remember before we break and I asked

12:58:44 22 you about the proper format and the proper steps for

12:58:46 23 this person to take and that included finding that it

12:58:50 24 had a different indications statement and then asking

12:58:50 25 the question if it raised new questions of safety and

12:58:53 1 effectiveness?

12:58:53 2 A. Right. But this is -- this is the --

12:58:57 3 This is an -- an expert reviewer applying it
12:59:00 4 to a product with his view of the data and information
12:59:07 5 and clinical usage.

12:59:08 6 Q. So he had a different view about what he
12:59:10 7 should be doing with this device than you did.

12:59:12 8 A. No.

12:59:12 9 MS. EATON: Object to the form of that
12:59:14 10 question.

12:59:16 11 A. No. He would have evaluated comparatively
12:59:18 12 the submission, the labeling and claims being made.

12:59:20 13 Q. Things like Exhibit 3.

12:59:22 14 A. Exactly.

12:59:22 15 Q. And those are the things that you indicated
12:59:24 16 to me would indicate to a reviewer that the
12:59:26 17 indications had changed; correct?

12:59:28 18 A. In -- in my interpretation I would think
12:59:31 19 that there's some differences, but does that create a
12:59:34 20 new -- to -- to me, would that create a new intended
12:59:39 21 use? My -- my response was no. To Glenn, Glenn was
12:59:42 22 saying --

12:59:42 23 Well, as I said -- said to you, the reviewer
12:59:47 24 may have a broader interpretation, so I gave you that
12:59:49 25 alternative. The reviewer may have a more broad

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12:59:53 1 interpretation and consider in-hospital use the same
12:59:56 2 indication use -- for use.

12:59:57 3 Q. I -- I just want to make sure I'm clear on
12:59:59 4 your testimony because I was pretty sure you had told
13:00:04 5 me that from your review of materials in this case and
13:00:04 6 from your review of materials like what's in front of
13:00:06 7 you, that the indications statement and the
13:00:08 8 indications for use on the Bair Hugger fif -- 500
13:00:11 9 versus the 200 had changed and that that would require
13:00:14 10 the FDA to ask if that raised new safety of -- safe --
13:00:18 11 new questions of safety and effectiveness. Do you
13:00:22 12 agree with that or not?

13:00:22 13 A. Well I don't think I expressed that in my
13:00:24 14 report, but as I view this here now, that could be my
13:00:29 15 approach. But it doesn't mean his approach is
13:00:33 16 invalid.

13:00:33 17 Q. And you see where it says "DO DIFFERENCES
13:00:35 18 ALTER THE EFFECT OR RAISE NEW ISSUES OF SAFETY OR
13:00:38 19 EFFECTIVENESS?" Do you see where it says that?

13:00:40 20 A. Yes.

13:00:41 21 Q. That question was not answered; correct?

13:00:43 22 A. Right. It wouldn't have to be answered.

13:00:45 23 Q. Right. Because you can skip it if you find
13:00:47 24 it has the same indications statement.

13:00:49 25 A. Correct.

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13:00:50 1 Q. Correct. So at no point at the approval of
13:00:54 2 the Bair Hugger 500 series did the FDA ever make a
13:00:56 3 determination of whether the new indications for use
13:00:59 4 in an operating room or any new indications for use
13:01:03 5 altered the effects or raised new safeties of safety
13:01:07 6 or effectiveness.

13:01:07 7 A. That point wasn't addressed in this
13:01:10 8 flowchart, but that's not to say, you know, identi --
13:01:14 9 the reviewer, Glenn Bird in this case, you know,
13:01:16 10 identifying the same indications statement, that he
13:01:21 11 didn't have the knowledge base of in-hospital use and
13:01:25 12 the safety factors related to in-hospital use
13:01:28 13 generally.

13:01:28 14 Q. That --

13:01:29 15 A. So -- so his knowledge base is different
13:01:31 16 than mine.

13:01:32 17 He's the reviewer here. He's the person
13:01:34 18 reviewing these things day in and day out. His
13:01:37 19 knowledge base is different from mine.

13:01:38 20 Q. Uh-huh.

13:01:39 21 A. He may well have stated, "OR use. Well we
13:01:43 22 know that, so no, same indication."

13:01:44 23 Q. You can't state any of what you've just said
13:01:46 24 to a reasonable degree of certainty because you would
13:01:48 25 be totally speculating about what Mr. Bird thought or

13:01:51 1 did not think; correct?

13:01:52 2 A. Not so much, because I can view any number
13:01:55 3 of 510(k)s and there may be some variations on a theme
13:01:57 4 from what I may consider, but it's --

13:02:00 5 It may be because it's a device that I
13:02:03 6 didn't -- I wasn't supervisory in control of, it is a
13:02:07 7 different knowledge base than I have, a different
13:02:09 8 expertise, so there may well be a different pathway
13:02:13 9 this reviewer followed.

13:02:14 10 Q. If you had given the opinion at some point
13:02:17 11 in today's deposition, if you had given testimony that
13:02:20 12 said the proper way to fill out this flowchart is to
13:02:22 13 answer number three "NO" and number four, answer that
13:02:26 14 question, this -- if that's what you said, this is not
13:02:30 15 consistent with that; right?

13:02:30 16 MS. EATON: Object to the form of the
13:02:31 17 question.

13:02:33 18 A. That would be my opinion in regard to my
13:02:36 19 particular expertise set.

13:02:37 20 Q. Okay. I'm going to talk to you a little bit
13:02:52 21 about the organization of your report, and as we
13:02:55 22 talked at the beginning, your report sets forth that
13:02:57 23 there were -- there were two basic things off the back
13:03:00 24 that you were asked to look at and then some things in
13:03:03 25 addition, and we'll go down into those. The first two

13:03:05 1 things that is listed in your report that you were
13:03:08 2 asked to do is to deliver opinions in response to
13:03:11 3 plaintiffs' master long form complaint and the report
13:03:14 4 of Yadin David; is that correct?

13:03:15 5 A. Right. As I always do, I'll --I'll look at
13:03:17 6 the complaint as -- as a starting point for -- to
13:03:20 7 understand what are the arguments and what am I trying
13:03:23 8 to address here.

13:03:24 9 Q. Okay.

13:03:25 10 A. And then any -- to rebut any expert report
13:03:28 11 that's been provided.

13:03:31 12 Q. Well I'm trying to figure out where in your
13:03:31 13 report in what you were asked to do does it talk about
13:03:35 14 any expert other than Yadin David.

13:03:40 15 A. Well it does --

13:03:41 16 Well, I think I talked about one other
13:03:45 17 expert, or two maybe, briefly, briefly, --

13:03:48 18 Q. Okay.

13:03:49 19 A. -- in aspects of my report.

13:03:51 20 Q. Okay. So we have --

13:03:52 21 In terms of what you are saying that's
13:03:54 22 addressing plaintiffs' experts, we have -- you have
13:03:58 23 first --

13:03:59 24 Okay. So first there's a section of your
13:04:01 25 report entitled rebuttal opinions to Dr. David.

13:04:03 1 A. Correct.

13:04:04 2 Q. Okay. So you will agree with me that you
13:04:06 3 reviewed Dr. David's report and that in this section
13:04:10 4 of your report you are addressing the opinions set
13:04:15 5 forth by Dr. David and explaining why you think
13:04:17 6 they're wrong.

13:04:17 7 A. Not --

13:04:18 8 MS. EATON: Object to the form of the
13:04:19 9 question.

13:04:19 10 A. Not totally, because in the -- in the body
13:04:23 11 of my report, before the rebuttal section, I also
13:04:25 12 address aspects that he commented on, so I make clear
13:04:29 13 in the rebuttal portion or in aspects of the rebuttal
13:04:33 14 that I've already commented on this and refer to that,
13:04:37 15 for example.

13:04:37 16 Q. Okay. So what I think I hear you saying is
13:04:40 17 that in other parts of your report, in the main part,
13:04:43 18 there are statements being made in that report that
13:04:45 19 are specifically linked to Dr. Yadin David's report.

13:04:47 20 A. I believe so, yes.

13:04:48 21 Q. Okay. And then there are statements in your
13:04:50 22 report that are linked to plaintiffs' motion for
13:04:53 23 punitive damages.

13:04:55 24 A. Correct.

13:04:55 25 Q. Okay. That's another thing that you are

13:04:57 1 re -- had reviewed and delivered opinions on.

13:04:59 2 A. Right. That was -- that was provided kind

13:05:05 3 of late in the game, so to speak, and -- and I wanted

13:05:06 4 to make sure that at that point in time I understood

13:05:10 5 again, because, you know, complaints will be modified

13:05:15 6 and things will be said, additional things, I wanted

13:05:17 7 to make sure I went through that, that -- if there was

13:05:20 8 anything new, and to try and hit those points as best

13:05:23 9 I could in summation.

13:05:25 10 Q. Now there are things in that punitive damage

13:05:28 11 report that don't have anything to do with plaintiffs'

13:05:31 12 experts; right?

13:05:31 13 MS. EATON: Object to the form of the

13:05:32 14 question.

13:05:35 15 A. I would --

13:05:36 16 Well, I'd have to look at that to say "yes"

13:05:38 17 or "no."

13:05:38 18 Q. Okay. In other words, there are materials

13:05:43 19 cited in the punitive damages motion that you reviewed

13:05:44 20 that were not in plaintiffs' expert reports.

13:05:48 21 A. Give me that again.

13:05:51 22 Q. We'll ask that one more time.

13:05:51 23 A. Sure.

13:05:52 24 Q. You reviewed plaintiffs' punitive damage

13:05:54 25 motion.

13:05:54 1 A. Yes.

13:05:55 2 Q. That included materials that were attached
13:05:58 3 to that motion, exhibits and -- and whatever was cited
13:06:01 4 in that motion.

13:06:01 5 A. Yes.

13:06:02 6 Q. Okay. Some of the materials cited in that
13:06:03 7 motion were also included in plaintiffs' expert
13:06:05 8 reports.

13:06:05 9 A. I believe so, yes.

13:06:08 10 Q. Some of those materials cited in the
13:06:09 11 punitive damage motion were not included in
13:06:11 12 plaintiffs' expert reports, they were new to you.

13:06:15 13 A. They may have been. I know that, as you
13:06:16 14 said, a lot of it referred to -- seemed to be
13:06:20 15 reflecting Dr. David's report and the positions he
13:06:24 16 took.

13:06:24 17 Q. Okay. Now there --

13:06:27 18 Like you say, there are other parts of your
13:06:29 19 report --

13:06:29 20 There's a brief mention of -- of William
13:06:31 21 Jarvis for instance.

13:06:33 22 A. Correct.

13:06:33 23 Q. Okay. So there is at least a portion -- a
13:06:36 24 portion of your report, an opinion somewhere in there
13:06:40 25 that is meant to direct and rebut the opinions of Dr.

13:06:41 1 William Jarvis.

13:06:43 2 A. Well I'd say indirectly -- directly, because
13:06:47 3 Dr. David pointed to, for example, the HICPAC meeting,
13:06:51 4 and -- and Dr. Jarvis also commented on that, this
13:06:58 5 very same thing, so it was just by happenstance that
13:06:59 6 they kind of overlapped at that point.

13:07:01 7 Q. Sure. Okay. And then there is material in
13:07:05 8 your expert report that is more addressing the general
13:07:07 9 allegations that were contained in plaintiffs' master
13:07:10 10 complaint; correct?

13:07:10 11 A. I think so.

13:07:11 12 Q. Okay. And then there are some materials in
13:07:14 13 your report that were not brought up by plaintiffs'
13:07:17 14 experts and not brought up in a master complaint and
13:07:19 15 not brought up in a punitive damage motion; correct?

13:07:22 16 MS. EATON: Object to the form of the
13:07:23 17 question.

13:07:23 18 A. I think that's the case, and -- but only in
13:07:26 19 one or two instances.

13:07:27 20 Q. Okay. In other words, let me try to -- just
13:07:32 21 to put it into, you know, a list of the kinds of
13:07:35 22 opinions you're giving in this case, and you can tell
13:07:38 23 me if you're giving them or not. One of the kinds of
13:07:40 24 opinions you're going to be giving in this case is
13:07:42 25 a -- is a rebuttal to Dr. Yadin David.

13:07:44 1 A. Correct.

13:07:44 2 Q. To a limited extent, one of the other
13:07:47 3 opinions you'll be giving is the rebuttal to Dr.
13:07:51 4 William Jarvis.

13:07:52 5 A. Very limited.

13:07:52 6 Q. Very limited, yes.

13:07:54 7 Just offhand, do you think there's anything
13:07:57 8 but the HICPAC minutes that relate to Dr. Jarvis? Do
13:08:00 9 you remember offhand? And I know there may --

13:08:01 10 If it's in the report, it's in the report.

13:08:01 11 A. You mean is there -- is there something else
13:08:02 12 in my report about --

13:08:03 13 Q. Yeah. Yeah. Do you even remember offhand?

13:08:05 14 A. I don't -- I don't think so.

13:08:06 15 Q. Okay.

13:08:06 16 A. I may be incorrect, but I don't think so.

13:08:07 17 Q. Sure. Sure. And I mean if it's in the
13:08:10 18 report, it's in the report.

13:08:10 19 A. Sure.

13:08:11 20 Q. I'm not holding you to that now. And
21 then --

13:08:13 22 So you have those. Then you also have
13:08:15 23 opinions that dir -- that are directed towards the
13:08:16 24 arguments raised in the punitive damage motion which
13:08:19 25 somewhat overlap in some cases with experts' reports.

13:08:21 1 A. Correct.

13:08:22 2 Q. And then you have more-general opinions
13:08:25 3 about the plaintiffs' complaint and perhaps what we
13:08:27 4 could just call Dr. -- Mr. Ulatowski's general
13:08:30 5 opinions.

13:08:30 6 MS. EATON: Object to the form of the
13:08:31 7 question.

13:08:31 8 Q. Is that fair?

13:08:33 9 A. I think that's fair enough.

13:08:34 10 Q. Okay. There is also quite a bit about a
13:08:40 11 discussion about Dr. Augustine. You're familiar with
13:08:43 12 who Dr. Augustine is.

13:08:44 13 A. Yes.

13:08:44 14 Q. And your report discusses certain activities
13:08:46 15 by Dr. Augustine and things that he's done over the
13:08:50 16 years.

13:08:50 17 A. Yes.

13:08:52 18 Q. Okay. That's not meant to address anything
13:08:52 19 in plaintiffs' expert reports; correct?

13:08:57 20 MS. EATON: Object to the form of the
13:08:57 21 question.

13:08:59 22 A. Well I think it's -- it's -- well I think
13:09:10 23 it's sparked by aspects of -- of other documents. For
13:09:17 24 example, if I speak of MDRs, medical device reports,
13:09:22 25 certainly that aspect is brought up in my discussion

13:09:26 1 of the warning letter to Arizant, and -- and -- and so
13:09:36 2 there's a relationship there, you know.

13:09:38 3 Q. Do any of the plaintiffs' experts that
13:09:40 4 you're rebutting, do they talk about the warning
13:09:42 5 letter to Arizant relating to burns?

13:09:44 6 A. Well Dr. David talks about FDA's interaction
13:09:48 7 with Arizant, and to me that opened the door to -- to
13:09:54 8 talk about as well, but -- but -- so --

13:09:59 9 Q. So your view is because Dr. David talks
13:10:02 10 about some regulatory aspects of the -- Arizant
13:10:04 11 dealing with the FDA, that that was somehow related to
13:10:08 12 Augustine and his actions related to the FDA?

13:10:12 13 A. Well there's a history here. We're talking
13:10:14 14 about a -- a -- 510(k) submissions, the performance of
13:10:19 15 these devices over time, so postmarket information
13:10:24 16 provided to FDA is very relevant in regards to -- to
13:10:28 17 this whole scenario.

13:10:29 18 Q. Okay. There's --

13:10:30 19 MS. EATON: And I just want to interject an
13:10:32 20 objection to the form of that question.

13:10:33 21 MR. BANKSTON: Okay.

13:10:33 22 Q. There is then --

13:10:35 23 There's some opinions, too, about
13:10:39 24 Augustine's delay in filing a MedWatch report until 30
13:10:43 25 days had passed since a complaint was filed. Do you

13:10:46 1 know that -- that part of your report?

13:10:47 2 A. Yes.

13:10:47 3 Q. Okay. And it's your opinion that Dr.

13:10:49 4 Augustine was acting unconscionably in waiting 30 days

13:10:54 5 to file an MDR report.

13:10:55 6 MS. EATON: Object to the form of the

13:10:56 7 question.

13:10:56 8 A. I think I used words of that type.

13:10:58 9 Q. Okay. Is it your testimony that the day a

13:11:02 10 re -- claim was filed, Dr. Augustine -- and he becomes

13:11:08 11 aware of it, that a claim is filed against another

13:11:09 12 company, he has an affirmative duty to file an MDR

13:11:12 13 report that day?

13:11:13 14 A. Could you repeat the question?

13:11:14 15 Q. Sure. If Augustine becomes aware that

13:11:17 16 there's a lawsuit against a device made by another

13:11:20 17 company, is -- on the day he becomes aware of that

13:11:23 18 complaint, is he obligated to file an MDR report?

13:11:26 19 A. No, not on the day, but within a certain

13:11:29 20 timeframe.

13:11:29 21 Q. And what timeframe is that?

13:11:31 22 A. It's a 30-day timeframe.

13:11:32 23 Q. And that's when mis -- Dr. Augustine

13:11:34 24 reported that; correct?

13:11:35 25 A. No. I think there were --

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13:11:36 1 There was a process there of -- of waiting
13:11:39 2 for the company to submit an MDR and then delaying the
13:11:45 3 submission to -- to impugn, in my view, the integrity
13:11:51 4 of the company.

13:11:52 5 Q. Okay. So in other words, you're saying that
13:11:55 6 it was improper for Dr. Augustine to wait for 3M to
13:12:00 7 fulfill any alleged obligations under that 30 days,
13:12:02 8 that he should have, if he wanted to file an MDR
13:12:05 9 report, should have filed it immediately when he knew
13:12:07 10 about it.

13:12:07 11 A. No, I'm not saying that. I'm saying his
13:12:10 12 motivation was not, in my view -- it's my opinion,
13:12:13 13 it's my report -- that in my view his motives were not
13:12:18 14 related to public health but rather to impugning the
13:12:22 15 integrity of the Bair Hugger manufacturer.

13:12:24 16 Q. Okay. You read Dr. Augustine's deposition?

13:12:27 17 A. Yes, I have.

13:12:27 18 Q. Okay. And do you use that deposition to
13:12:29 19 support your opinions that you think he had an
13:12:31 20 improper motive?

13:12:32 21 A. Oh, I think so. Sure.

13:12:39 22 Q. There is a section of your report that
13:12:41 23 discusses 20 MDRs for the Hot Dog device.

13:12:44 24 A. Yes.

13:12:44 25 Q. What's that relevant to?

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13:12:46 1 A. It's relevant inasmuch as I discuss it in my
13:12:49 2 report, which is --

13:12:51 3 Well, if I'm going to be talking about
13:12:53 4 Arizant or 3M or Augustine -- whatever the timeframe
13:12:57 5 is -- reporting to FDA, then I want to take a look at
13:13:03 6 Hot Dog, which is Dr. Augustine's device, and to see
13:13:08 7 on a comparative basis what are the adverse outcomes
13:13:12 8 being reported to FDA. And, you know, I state what I
13:13:15 9 state in my report, that absent the litigation report,
13:13:20 10 it's my view that the numbers of MDRs would have been
13:13:23 11 about the same between the two companies.

13:13:25 12 Q. Why does it matter what MDRs were filed
13:13:29 13 about some other device that's not subject to this
13:13:31 14 lawsuit? What is that important to?

13:13:33 15 A. I -- I think it -- it sets the context
13:13:36 16 for -- for the -- as I do often in device reports, is
13:13:43 17 to look at competing devices, to look at their
13:13:46 18 performance of devices vis-a-vis others and see how
13:13:49 19 they compare. So, you know, I think it's very
13:13:51 20 relevant. I think it's important.

13:13:53 21 Q. What other devices did you look at in terms
13:13:58 22 of MDR reports?

13:13:58 23 A. I looked at the Hot Dog.

13:14:01 24 Q. What other devices?

13:14:01 25 A. I don't think I looked at other devices.

13:14:03 1 Q. So in terms of looking at competitive
13:14:05 2 devices, it was solely limited to Dr. Augustine's
13:14:07 3 device.

13:14:08 4 A. I believe so.

13:14:08 5 Q. Which isn't a device that's mentioned in Dr.
13:14:11 6 David's report; right?

13:14:12 7 A. I don't know if he talks about the Hot Dog
13:14:16 8 at all. You know, proba -- interestingly, probably
13:14:21 9 not, but I -- I can't be exactly sure of that.

13:14:24 10 Q. He talks about four other devices; right?

13:14:27 11 A. Correct.

13:14:28 12 Q. Did you search any MDRs for those devices?

13:14:31 13 A. No. Because I think a couple of them were
13:14:34 14 relatively new; there wouldn't be a history of -- a
13:14:38 15 coincidental history of MDR submissions. No, I didn't
13:14:41 16 look at them is the short answer.

13:14:42 17 Q. You're -- you're -- you're also testifying
13:14:45 18 that those four devices, you think that certain of
13:14:46 19 them are new devices. What do you mean by that?

13:14:49 20 A. Well a couple of them are relatively new
13:14:52 21 devices. I -- I can't recall the -- the marketing
13:14:55 22 data of all them, but the point is I did not look at
13:14:58 23 the MDRs for their devices.

13:15:01 24 Q. Okay. In terms of the MDR reporting for the
13:15:04 25 Bair Hugger, is that Augustine's obligation or 3M's

13:15:07 1 obligation?

13:15:09 2 A. Well that's ultimately 3M's obligation, but
13:15:13 3 it doesn't prevent, depending on --

13:15:16 4 You know, there's reporting requirements for
13:15:18 5 various parties, not just the manufacturer. There's
13:15:22 6 health -- healthcare facility reporting and there's
13:15:26 7 importer reporting, those are required reports, and
13:15:29 8 there's voluntary reports by -- by virtually any other
13:15:34 9 person. So, you know, that's the structure of
13:15:37 10 reporting to FDA.

13:15:41 11 Q. Have you been retained to offer opinions on
13:15:44 12 Augustine's motives? Is that one of the things that
13:15:46 13 you're retained to do?

13:15:50 14 A. That's an opinion I generated based upon my
13:15:53 15 analysis of the MDR data and his deposition. And I --
13:15:57 16 I explored it because, you know, FDA's been in kind of
13:16:03 17 the midst of this MDR reporting issue recently. It
13:16:09 18 was a subject of a recent inspection. There's been
13:16:13 19 correspondence with FDA. I felt I'd like to take a
13:16:17 20 look myself to see what's going on with this MDR
13:16:19 21 reporting, whether there's anything there there, and
13:16:21 22 so I looked at it.

13:16:23 23 Q. You're talking about Augustine's MDR
13:16:26 24 reporting with respect to the Bair Hugger; correct?

13:16:27 25 A. Yes.

13:16:28 1 Q. Not his MDR reporting with respect to the
13:16:31 2 Hot Dog.

13:16:32 3 A. Correct.

13:16:32 4 Q. Okay. Any of the plaintiffs' experts that
13:16:35 5 address Augustine or his motives in this litigation?

13:16:38 6 A. Any plaintiff. Well --

13:16:40 7 Q. Did you come across anything in reviewing
13:16:42 8 plaintiffs' expert reports about Augustine or his
13:16:45 9 motives?

13:16:46 10 A. I don't believe so.

13:16:47 11 Q. Okay. Can -- can you flip to page 25 of
13:17:09 12 your report for me.

13:17:10 13 A. Sure.

13:17:18 14 Q. Okay. At the top paragraph, in the second
13:17:22 15 line it says, "...I reserve the right to supplement
13:17:26 16 this report and my opinions after that reviewed is
13:17:30 17 completed and as discovery progresses in this
13:17:33 18 litigation." Correct?

13:17:34 19 A. Yes.

13:17:34 20 Q. Okay. From where do you get the ability to
13:17:38 21 reserve that right do you believe?

13:17:40 22 A. As new information is provided --

13:17:42 23 Q. Okay.

13:17:43 24 A. -- and they provide me an opportunity to
13:17:45 25 modify my opinions or supplement my opinions.

13:17:48 1 Q. You understand general discovery in this
13:17:51 2 case for general causation is closed; correct? Have
13:17:54 3 you been told that?

13:17:55 4 A. No, I haven't been told that.

13:17:56 5 Q. Okay. And you understand the parties from
13:17:57 6 here on out are going to be doing discovery on the
13:18:01 7 specific cases and these specific patients; right?

13:18:03 8 A. I suspect.

13:18:04 9 Q. Okay. Do you have any reason to think at
13:18:05 10 all that additional discovery on what happened to
13:18:08 11 these particular patients is going to be in any way
13:18:11 12 relevant to your opinions about whether the company,
13:18:13 13 in working with the device, complied with FDA
13:18:16 14 regulations?

13:18:17 15 A. I have no idea. Possibly.

13:18:20 16 Q. Can you give me a detail of a plaintiff's
13:18:20 17 surgery that could perhaps be relevant to your
13:18:23 18 regulatory opinions?

13:18:24 19 A. Repeat the question again.

13:18:25 20 Q. Can you give me a detail of plaintiff's
13:18:29 21 surgery that could be relevant to your -- that could
13:18:31 22 change or alter your regulatory opinions?

13:18:33 23 A. Well I can't foresee it at this time, not to
13:18:36 24 say there isn't.

13:18:45 25 Q. Are you going to be offering any opinions on

13:18:47 1 the individual plaintiffs?

13:18:50 2 A. I -- I would suspect not in regards to
13:18:54 3 clinical aspects or any other aspect. There may be
13:19:00 4 aspects, for example, of --

13:19:05 5 Well, I -- I guess I don't want to
13:19:08 6 speculate.

13:19:15 7 Q. Okay. I want to talk to you about a section
13:19:16 8 of your report that discusses the definition of
13:19:18 9 "safe."

13:19:18 10 A. Sure.

13:19:19 11 Q. And that there's one definition of "safe"
13:19:21 12 that applies to medical devices; correct?

13:19:23 13 A. Correct.

13:19:24 14 Q. Okay. Let's turn to page 31 so we can look
13:19:27 15 at that definition together.

13:19:36 16 On page 31 you state that the one definition
13:19:38 17 of "safe" that applies to medical devices is as
13:19:41 18 follows: 'There is reasonable assurance that a device
13:19:45 19 is safe when it can be determined, based upon valid
13:19:49 20 scientific evidence, that the probable benefits to
13:19:52 21 health from the use of the device for its intended
13:19:55 22 uses and conditions of use, when accompanied by
13:19:59 23 adequate directions and warnings against unsafe use,
13:20:03 24 outweigh any probable risk.'" That's your definition
13:20:06 25 that you're using in this case; correct?

13:20:07 1 A. That's correct.

13:20:08 2 Q. Okay. You have already told me today that

13:20:12 3 you're not going to be giving the jury an opinion

13:20:13 4 within a degree of -- reasonable degree of medical

13:20:16 5 certainty that there is valid scientific evidence of

13:20:18 6 probable health benefits from the use of the Bair

13:20:21 7 Hugger in orthopedic surgeries; correct?

13:20:27 8 A. I believe so. The aspect of safety that I

13:20:31 9 address in my report is in regard to my response to

13:20:36 10 Dr. David. As -- as you know, in reading my report,

13:20:42 11 that -- that his report is devoted to risk without any

13:20:47 12 discussion of benefit.

13:20:49 13 Q. Okay. So the -- the answer is no, you're

13:20:52 14 not going to be giving that opinion to the jury.

13:20:54 15 A. I'll discuss it from a regulatory point of

13:20:56 16 view that safety is based upon benefit versus risk,

13:20:59 17 and Dr. David discusses risk.

13:21:01 18 Q. Right. And -- and I understand that you're

13:21:02 19 going be to giving opinions about what the regulations

13:21:06 20 require and about the existence of this definition;

13:21:07 21 right? That's something that's --

13:21:09 22 You would agree that this is something that

13:21:11 23 the regulations inform, this definition.

13:21:13 24 A. Correct.

13:21:13 25 Q. Okay. But in terms of whether you can have

13:21:16 1 medical testimony about whether there is actually
13:21:19 2 valid scientific evidence of a probable risk, you've
13:21:22 3 told me today that's not an opinion you're going to be
13:21:25 4 giving the jury.

13:21:25 5 A. I will defer to experts, clinical experts on
13:21:28 6 that matter.

13:21:28 7 Q. Okay. And -- and the same answer was true
13:21:30 8 with regard to an opinion within a reasonable degree
13:21:34 9 of medical certainty about the degree of medical risk
13:21:36 10 from the use of the Bair Hugger in orthopedic
13:21:37 11 surgeries.

13:21:39 12 MS. EATON: Object to the form of the
13:21:40 13 question.

13:21:40 14 A. In regard to medical risk, yes.

13:21:42 15 Q. Yes. Okay.

13:21:43 16 A. There are vari -- various aspects of risk,
13:21:47 17 medical risk, yes.

13:21:47 18 Q. Sure. So when we talk about this definition
13:21:50 19 of "safe" which requires a finding of valid scientific
13:21:53 20 evidence supporting probable benefits to health and
13:21:56 21 also a finding concerning any probable risks in
13:22:00 22 connection with its intended use and its conditions of
13:22:02 23 use, that's not testimony you are qualified to give.
13:22:06 24 That's somebody else.

13:22:07 25 A. From a medical position.

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13:22:09 1 Q. Correct. So by your definition, you are not
13:22:13 2 going to be testifying in this case that there is a
13:22:17 3 reasonable assurance from a medical point of view that
13:22:18 4 the device is safe.

13:22:22 5 A. I don't think I address that in my report
13:22:24 6 head on.

13:22:25 7 Q. And I -- uh-huh. And so I just want to
13:22:28 8 confirm that's not an opinion you're going to be
13:22:31 9 giving.

13:22:31 10 A. That's correct.

13:22:31 11 Q. Okay. I want to talk to you about your
13:22:35 12 opinion that 3M was appropriate in not considering the
13:22:42 13 MDR reports that were based on litigation because they
13:22:46 14 would not reasonably suggest to the company that there
13:22:48 15 was an event, in basic shorthand. Do you agree that's
13:22:52 16 essentially your opinion?

13:22:53 17 MS. EATON: Let me object to the form of the
13:22:54 18 question.

13:22:55 19 MR. BANKSTON: What's wrong on that one?

13:22:58 20 MS. EATON: The word "considering."

13:22:58 21 MR. BANKSTON: Okay.

13:22:58 22 MS. EATON: I object to that word. I don't
13:23:00 23 think it's accurate.

13:23:00 24 MR. BANKSTON: Okay. Let's -- let's get
13:23:02 25 that from your report. That's in your report.

13:23:06 1 MS. EATON: At least how I heard you use it.

13:23:59 2 MR. BANKSTON: I need a better word to

13:24:00 3 search for.

13:24:08 4 Q. All right, here we go. Let's go to page 65.

13:24:12 5 A. Okay. All right.

13:24:20 6 Q. All right. This is the opinion that I was

13:24:23 7 quoting, it's at the very bottom of the page, and you

13:24:23 8 will see in the second sentence in the last paragraph,

13:24:26 9 "It is my opinion that 3M appropriately did not

13:24:30 10 consider the litigation-based complaints to

13:24:33 11 'reasonably suggest' that a Bair Hugger may have

13:24:35 12 caused or contributed to an infection." That's your

13:24:37 13 opinion in this case?

13:24:38 14 A. Right. Correct. Yes.

13:24:40 15 Q. All right. So part of what we're saying --

13:24:44 16 what is being said in this report, and I think you'll

13:24:47 17 see from the -- the following sentences, is that the

13:24:50 18 litigation-based complaints and the associated

13:24:53 19 MedWatch reports submitted by Dr. Augustine are

13:24:56 20 tainted because they're unverified, they're

13:24:58 21 incomplete, have motive ascribed to them. There's

13:25:01 22 reasons to dismiss them in other words.

13:25:03 23 A. Yes.

13:25:03 24 Q. Okay. And in fact if a complete is

13:25:11 25 unverified and incomplete --

1 THE REPORTER: I'm sorry?

2 MR. BANKSTON: No problem. I can do it

13:25:11 3 again.

13:25:11 4 MS. EATON: Can you stop for a moment?

13:25:13 5 Because I'm -- I'm not able to follow this (referring

13:25:14 6 to realtime screen). What did I need to click?

13:25:16 7 Okay. Now I think it's working.

13:25:18 8 (Discussion off the stenographic record.)

13:25:22 9 Q. Let's start that question again, which is

13:25:25 10 essentially: Part of your opinion is that because

13:25:27 11 these reports are incomplete and unverified, it's

13:25:33 12 impossible to tell if the device did or did not cause

13:25:36 13 an injury.

13:25:39 14 A. No. It's the -- it's the sum of my

13:25:41 15 statement, which it's been biased and contrived by Dr.

13:25:49 16 Augustine that -- generated and -- and precipitated by

13:25:53 17 Dr. Augustine in this really extraordinary, outrageous

13:25:59 18 process he had, that in my years at FDA is

13:26:02 19 unprecedented. And boy, I'll -- I'll say that in

13:26:08 20 court without any -- any deviation or hesitance.

13:26:13 21 Un -- unmatched in my experience, in my FDA experience

13:26:18 22 evaluating MDRs, taking action on MDRs or not taking

13:26:23 23 action on MDRs, I've never seen anything like -- like

13:26:25 24 this. And -- and so given all that, for 3M -- and

13:26:32 25 then FDA inspecting 3M based upon a complaint by

13:26:38 1 probably Dr. Augustine, and then FDA being apprised
13:26:43 2 again through correspondence, 3M was very visible on
13:26:47 3 this with FDA about their -- their position without
13:26:52 4 response from FDA to the negative that, you know,
13:26:57 5 these -- it was --

13:26:58 6 These reports are not reasonable and should
13:27:00 7 not be reported.

13:27:01 8 Q. Okay. My question is: If an MDR report is
13:27:04 9 submitted and it has -- and it's incomplete and
13:27:07 10 unverified, that makes it difficult or maybe even
13:27:10 11 impossible to tell if the device did or did not cause
13:27:13 12 the injury.

13:27:14 13 A. As a general rule, that's possible, yes.

13:27:16 14 Q. Okay. And if the company can't tell whether
13:27:18 15 the device did or did not cause the injury, they don't
13:27:21 16 have to report it.

13:27:24 17 A. No. The -- the rule is if -- if there's
13:27:29 18 reasonable evidence that the device may have caused or
13:27:33 19 contributed to certain events, may have caused or
13:27:38 20 contributed, then it's reportable unless there is
13:27:41 21 evidence to the contrary.

13:27:42 22 Q. Okay.

13:27:42 23 A. The keyword here is -- is "reasonable"
13:27:46 24 evidence, and -- and that's the linchpin here that Dr.
13:27:52 25 Augustine has undermined the process.

13:27:55 1 Q. Okay. So in other words, because of the
13:27:59 2 tainting influence of Dr. Augustine --

13:28:02 3 I'll correct you just for going forward:
13:28:05 4 For the record, his name is Augustine.

13:28:07 5 A. Okay. Augustine. Sorry.

13:28:10 6 Q. Yeah. It's not -- yeah, confuses. Plenty
13:28:10 7 of people named Augustine, too.

13:28:11 8 A. Well, you know, I'm Catholic. St.
13:28:13 9 Augustine.

13:28:14 10 Q. Right. Yes.

13:28:15 11 Because of this taint of Dr. Augustine,
13:28:19 12 you're saying that there's no way these -- these
13:28:22 13 reports could be accurate, or are you saying that
13:28:24 14 because of the taint of Augustine there's significant
13:28:27 15 reason to doubt these reports?

13:28:29 16 A. The -- the latter. Because of -- because of
13:28:32 17 the manner in which these were generated were -- and
13:28:38 18 how this was all set up, that that's what tainted,
13:28:43 19 that they should be disregarded as -- as unreasonably
13:28:46 20 submitted. And -- and, you know, the fact of the
13:28:49 21 matter is FDA hasn't said anything to the contrary.

13:28:52 22 Q. Okay. So what that brings us to is that Dr.
13:29:00 23 Augustine's reports and his influence in it and his
13:29:03 24 tainting influence in it means there's significant
13:29:06 25 reason to doubt these reports, and therefore, while

13:29:10 1 you probably can't say for sure it didn't cause these
13:29:12 2 incidents, it probably didn't cause these incidents.
13:29:16 3 That would be a fair conclusion for the company to
13:29:17 4 reach?

13:29:18 5 MS. EATON: Object to the form of the
13:29:19 6 question.

13:29:22 7 A. I -- I think that --

13:29:25 8 Well my answer is I think if -- if there
13:29:29 9 were other methodologies for submitting these reports,
13:29:32 10 if the patients had submitted them, if the patient's
13:29:35 11 doctor had submitted them, if a patient's lawyer,
13:29:38 12 without the undue influence from Dr. Augustine, had
13:29:46 13 submitted them, then -- then there may be more
13:29:50 14 credibility to them. But this is -- it -- it's almost
13:29:53 15 without thought that -- that these were submitted
13:29:59 16 just -- just as a matter of -- of pumping up the
13:30:02 17 numbers of MDRs for no public-health reason but solely
13:30:06 18 to, in my view, my opinion, to -- to create this
13:30:11 19 impression of the Bair Hugger device. Well that's not
13:30:14 20 the purpose of the MDR reporting process.

13:30:17 21 Q. Well I'm really trying to specifically
13:30:18 22 address what this taint from Dr. Augustine would make
13:30:22 23 a reasonable company conclude, and would it --

13:30:24 24 What I'm trying to understand is: That
13:30:27 25 taint makes them feel that there's, as you said,

13:30:30 1 credibility issues with this. That's one thing they
13:30:32 2 would notice as you're saying; correct?

13:30:34 3 A. Yes. We'll have to let the chips fall where
13:30:37 4 they may on any specific plaintiff once the evidence
13:30:40 5 comes to bear, once the clinical evidence, the usage
13:30:43 6 of Bair Hugger or non-usage or how it was used, when
13:30:46 7 it was used, the clinical condition of the plaintiff,
13:30:50 8 all that stuff comes to bear in a -- in a trial, well,
13:30:53 9 you know, then -- then we'll know more, perhaps, or we
13:30:57 10 may know even less.

13:30:58 11 Q. Sure. Okay. So in the future --

13:31:01 12 Let me see if you'd agree with my statement
13:31:03 13 right now. Right now, because of these tainted MDR
13:31:06 14 reports, which have, according to you, significant
13:31:09 15 problems, right now the company cannot say with any
13:31:13 16 authority what happened with any particular patient,
13:31:17 17 they can't say with authority that the device did or
13:31:20 18 did not cause the injury, they have very significant
13:31:23 19 reason to doubt it. Is that fair?

13:31:26 20 MS. EATON: Object to the form of the
13:31:27 21 question.

13:31:27 22 A. What I'll say is I -- I think the evidence
13:31:29 23 will have to be brought to bear for a more clear
13:31:34 24 finding of root cause --

13:31:36 25 Q. Okay.

13:31:36 1 A. -- of a particular clinical event.

13:31:38 2 Q. If --

13:31:39 3 In other words, as we go further and more
13:31:41 4 evidence comes out and as we look closer at these
13:31:44 5 events and apply scrutiny to them, we may be able to
13:31:47 6 come to a firm conclusion that this device did not
13:31:50 7 cause these injuries.

13:31:52 8 A. That may well be the case.

13:31:54 9 Q. That's --

13:31:55 10 A. I think --

13:31:55 11 Q. That's down the road.

13:31:56 12 A. Yes. But -- but -- yes. But in addition,
13:31:59 13 look, we -- we have an -- an allegation of infection
13:32:03 14 reported in these reports, and boom, right away it's
13:32:07 15 the Bair Hugger. Well I'm sorry, there's lots of
13:32:11 16 stuff in an OR, there's lots of things going on in an
13:32:14 17 OR, and to -- to pinpoint the Bair Hugger is -- is
13:32:20 18 really extraordinary in MDR reports.

13:32:22 19 You know, what I will see is, depending on
13:32:24 20 the device, you'll see some greater definition of
13:32:28 21 causation because of the particular infection or
13:32:31 22 outcome of the patient and there won't be a jumping to
13:32:34 23 conclusions.

13:32:35 24 MR. BANKSTON: Okay. I'm going to have to
13:32:37 25 object as non-responsive.

13:32:41 1 Q. If that's further down the road, you're
13:32:44 2 going to -- you would agree with me that right -- that
13:32:46 3 off the basis of the MDR reports themselves, just from
13:32:49 4 those, just from the reports the manufacturer received
13:32:52 5 before you ever got involved in the case or any of
13:32:55 6 this ever happened right here, that at that moment
13:32:58 7 from those MDR reports, the company did not have
13:33:01 8 sufficient information to conclude conclusively that
13:33:03 9 the device did not cause these injuries. That's still
13:33:07 10 an open question even sitting here right now. And I
13:33:09 11 understand you think that they most probably did not,
13:33:12 12 but can you point me to any information in those MDR
13:33:15 13 reports that says -- would be used for a conclusion
13:33:18 14 that these absolutely did not cause the problem?

13:33:23 15 MS. EATON: Object to the form of the
13:33:23 16 question.

13:33:23 17 A. You're asking about an absolute situation,
13:33:27 18 and -- and there are -- there's no absolutes in
13:33:29 19 medicine. But what I'm also saying is for any given
13:33:36 20 plaintiff, the facts will -- may bear out a more
13:33:40 21 likely causation or even more lack of determination of
13:33:47 22 what actually caused it.

13:33:48 23 Q. We had been talking about experts who are
13:33:52 24 qualified in medical things, a lot of them involved in
13:33:55 25 this case. You've seen some of their reports.

13:33:56 1 There's defendants' experts, too. Would you think
13:34:00 2 that -- that you could have a person who is medically
13:34:05 3 qualified and that person could be presented with
13:34:07 4 evidence, and then that person, using medical
13:34:10 5 judgment, could conclude that this device did not
13:34:13 6 cause these injuries? That's something that's
13:34:15 7 possible in your mind?

13:34:16 8 A. Yes.

13:34:16 9 Q. Okay. That's -- that's not what Arizant was
13:34:21 10 doing in terms of the MDR. They weren't trying to
13:34:25 11 conclusively prove that the product didn't cause these
13:34:28 12 injuries. You're saying that because they doubted the
13:34:32 13 reports because the reports had significant problems,
13:34:35 14 they were non-reportable.

13:34:36 15 A. They were --

13:34:37 16 MS. EATON: Object to the form of the
13:34:38 17 question.

13:34:38 18 A. These were form-letter MDRs --

13:34:40 19 Q. Okay.

13:34:42 20 A. -- from Dr. Augustine.

13:34:42 21 Q. Okay. So what I --

13:34:43 22 A. They -- they -- they weren't individualized
13:34:46 23 accounts of events. These were precooked testimonies
13:34:52 24 of -- of his theory.

13:34:53 25 Q. Okay. So in other words, when making the

13:34:56 1 decision about re --

13:34:57 2 When receiving those MDR reports and making
13:34:59 3 the decision about whether to report, Arizant was not
13:35:03 4 quali -- was not required by law to have a medical
13:35:08 5 person deliver a medical judgment or a medical opinion
13:35:12 6 that this device did not cause these injuries.

13:35:15 7 A. Well that is one of the -- the -- one of the
13:35:20 8 processes in an MDR analysis, --

13:35:22 9 Q. Okay. So --

13:35:23 10 A. -- that a -- that a medical doctor -- excuse
13:35:25 11 me -- a medical doctor, a biomedical engineer or a
13:35:29 12 health professional such as a nurse can make decisions
13:35:32 13 of that type, that the device conclusively did not --
13:35:37 14 the device was not involved in the event. But the
13:35:39 15 regulation provides enough flexibility and
13:35:43 16 interpretation for 3M to say, look, based on the facts
13:35:47 17 that -- that we're seeing here, these were all
13:35:51 18 contrived and -- and are unreasonable. And FDA has
13:35:53 19 not concluded otherwise, so --

13:35:55 20 And believe me, I think, you know, being
13:35:58 21 director of compliance for so many years, if FDA
13:36:01 22 thought other -- if I thought otherwise as director of
13:36:03 23 compliance, and I -- I would be the one that made that
13:36:06 24 decision, I would have jumped on 3M right away. And
13:36:08 25 that's not been the case.

13:36:09 1 Q. Are you testifying that in making decisions
13:36:12 2 about MDR reporting, the company had sufficient
13:36:16 3 information to lead a medical individual to conclude,
13:36:19 4 about all of those surgeries that were reported, that
13:36:21 5 the devices did not cause those injuries?

13:36:25 6 A. You're -- you're asking about a process
13:36:29 7 that --

13:36:29 8 3M actually identified and assessed the
13:36:31 9 reasonableness of the submission, and they -- as has
13:36:36 10 been expressed in deposition testimony, as has been
13:36:38 11 expressed at FDA, and 3M has never attested to the
13:36:41 12 fact that they made a -- at least I don't think so --
13:36:44 13 ever made a -- conducted a medical opinion of the
13:36:48 14 reports because you couldn't even get that far because
13:36:51 15 the reports were so contrived as to be, really,
13:36:55 16 medically not -- not yet valuable for that purpose.

13:36:58 17 Q. So they had reports that alleged that the
13:37:01 18 product may have caused an injury and they did not at
13:37:05 19 that time have medical opinions saying that the device
13:37:08 20 did not cause the injury.

13:37:10 21 A. I may be incorrect, but I -- I don't -- I'm
13:37:13 22 not --

13:37:13 23 I'd have to look at deposition testimony
13:37:15 24 again, but I'm not sure they have that analysis for
13:37:19 25 each of the MDRs. That analysis -- position, as I

13:37:24 1 understand it and as I concluded, too, was that -- was
13:37:28 2 the unreasonableness of the submissions. And, you
13:37:32 3 know, once again, FDA evaluated their thought process,
13:37:35 4 their procedures, their rationale for not submitting
13:37:39 5 the MDRs, and have not concluded that they should be
13:37:44 6 submitted.

13:37:44 7 Q. In order --

13:37:45 8 Put it this way: If a medical -- medical
13:37:48 9 device manufacturer is in possession of an MDR
13:37:52 10 report -- or excuse me. Let's -- that's just not the
13:37:54 11 correct terminology.

13:37:55 12 If a medical device manufacturer is in
13:37:57 13 possession of an allegation of a patient injury from
13:38:00 14 their device and that medical device manufacturer does
13:38:04 15 not currently possess information that would lead a
13:38:07 16 person who's qualified to make a medical judgment to
13:38:10 17 conclude that the device did not cause or contribute
13:38:12 18 to the death, if they don't have that information,
13:38:15 19 that event is reportable. Agreed?

13:38:17 20 A. In the normal course of events. But this is
13:38:20 21 very abnormal, as I stated. This is unprecedented.

13:38:23 22 Q. So because this situation to you is un -- is
13:38:25 23 abnormal, we can ignore the letter of the law.

13:38:28 24 MS. EATON: Object to the form of the
13:38:29 25 question.

13:38:29 1 A. No, no. No. We're consistent with the law
13:38:31 2 in that are the reports reasonable? That's part of
13:38:34 3 the definition of -- of the decision process. And a
13:38:39 4 reasonable report is one independently submitted by a
13:38:45 5 manufacturer, healthcare facility or importer
13:38:50 6 attesting to what I'll call a complaint, and -- and
13:38:54 7 that being evaluated by the manufacturer.

13:38:56 8 Q. Let's -- let's try to -- let's try to take
13:38:59 9 it into the hypothetical sphere for a moment and to
13:39:03 10 say: If Arizant possessed information that could
13:39:07 11 reasonably suggest that a device caused or even may
13:39:13 12 have caused an injury, it has to report that unless
13:39:16 13 it's in possession of information that would lead a
13:39:19 14 medical professional to conclude that the device did
13:39:24 15 not cause the injury.

13:39:24 16 MS. EATON: Object to the form of the
13:39:24 17 question.

13:39:25 18 A. Well the regulation is as it is. In the
13:39:27 19 normal course, as typically occurred day in and day
13:39:33 20 out at FDA, doctors, hospitals, manufacturers submit
13:39:36 21 reports with MDRs based on complaints provided to
13:39:40 22 them. So that occurs every day, day in, day out, and
13:39:44 23 that's -- that's the way reporting normally ensues.
13:39:47 24 This -- this is quite -- quite an extraordinary
13:39:50 25 animal here.

13:39:50 1 Q. It is your opinion that because this is an
13:39:55 2 abnormal situation or because Augustine's taint was
13:40:03 3 involved in this situation, that even though the
13:40:07 4 company was in possession of an allegation that their
13:40:11 5 product may have caused an injury, it -- because it
13:40:13 6 was abnormal, it did not need to be in possession of
13:40:17 7 information that would lead a medical professional to
13:40:20 8 conclude it did not cause the injuries?

13:40:21 9 A. No, I -- I think it provided a foundation
13:40:24 10 for -- for not reporting until I believe at such time
13:40:28 11 other evidence comes to bear that can be relied upon
13:40:32 12 and can be assessed by 3M, and then, again, a
13:40:37 13 reporting decision can be made.

13:40:39 14 Q. Okay.

13:40:45 15 MS. EATON: When you have a stopping point,
13:40:47 16 I need to take a break.

13:40:49 17 MR. BANKSTON: Yeah, we can take a break.

13:40:51 18 THE REPORTER: Off the record, please.

13:46:50 19 (Recess taken.)

13:46:50 20 BY MR. BANKSTON:

13:46:50 21 Q. I want to talk a little bit about your
13:46:52 22 report again, if you want to pull that out.

13:46:54 23 A. Okay.

13:46:54 24 Q. Let's go to page 55.

13:46:57 25 A. Fifty-five. Okay.

13:47:03 1 Q. All right. And you see this opinion that
13:47:05 2 begins at number seven?

13:47:06 3 A. Yes.

13:47:07 4 Q. Okay. And what is this opinion just
13:47:09 5 generally about?

13:47:10 6 A. It's about the MedWatch report.

13:47:11 7 Q. Okay. Now go straight through -- flip to
13:47:15 8 about page 66, and all of these pages between here and
13:47:20 9 66, those are dealing with opinion number seven;
13:47:23 10 correct?

13:47:23 11 A. Right.

13:47:23 12 Q. Okay. And you'll agree with me that there
13:47:26 13 are no opinions disclosed by plaintiffs' experts about
13:47:28 14 MDR reporting.

13:47:34 15 A. No. I think we talked about that already.

13:47:36 16 Q. Yeah. I just want to make sure I have that
13:47:38 17 correct. Just from the standard of plaintiffs'
13:47:40 18 experts, we talked about --

13:47:41 19 Well, and just to confirm, we talked about
13:47:43 20 Augustine. There was no plaintiffs' opinions about
13:47:45 21 Dr. Augustine; right?

13:47:46 22 A. No.

13:47:46 23 Q. And likewise, MDR reporting in general,
13:47:50 24 there's no reports and nothing in plaintiffs' reports
13:47:53 25 about MDR reporting.

13:47:55 1 MS. EATON: Object to the form of the
13:47:58 2 question.

13:47:58 3 MR. BANKSTON: What's your objection?

13:47:59 4 MS. EATON: I think that mischaracterizes
13:48:00 5 what he said, but I'd have to go back and look.

13:48:03 6 MR. BANKSTON: Okay.

13:48:03 7 A. I -- I don't believe so. I might be
13:48:04 8 incorrect, but I -- I don't believe so.

13:48:04 9 Q. In other words, these are your opinions, not
13:48:07 10 something in response to plaintiffs' expert opinions.

13:48:09 11 A. This is my opinion, yeah, because --

13:48:11 12 You know, if there was a setup for a
13:48:13 13 plaintiffs' expert, I would have said so.

13:48:15 14 Q. Okay.

13:48:16 15 A. Well it says here, for example, on seven,
13:48:19 16 "The Complaint...alleges that 3M/Arizant failed to
13:48:22 17 conduct surveillance of the Bair Hugger."

13:48:24 18 Q. Okay. That's about the complaint, correct,
13:48:26 19 not --

13:48:26 20 A. Right.

13:48:26 21 Q. -- the plaintiffs' expert reports?

13:48:29 22 A. Right.

13:48:29 23 Q. Okay.

13:48:30 24 A. And so that -- you know, I was going to --

13:48:32 25 And then there was ample deposition

13:48:35 1 testimony due to questioning posed by plaintiffs'

13:48:39 2 attorney, maybe one of you -- you two, so obviously

13:48:42 3 it's -- it's of interest to you two in one form or

13:48:45 4 another, so I felt it's important to address it.

13:48:49 5 Q. Sure. And -- and I'm not -- not trying to

13:48:52 6 make any judgments about what you did, I'm just trying

13:48:54 7 to figure out what they are. And in this case, these

13:48:57 8 are opinions, like we say, addressed in the complaint

13:49:01 9 and not -- where those are organized instead of

13:49:05 10 plaintiffs' experts.

13:49:05 11 A. Right. I don't think Dr. David discusses

13:49:08 12 MDRs except --

13:49:16 13 No. I don't think he discusses the 2016

13:49:19 14 inspection.

13:49:19 15 Q. Okay.

13:49:21 16 A. But certainly he talks about the 20 -- 2010

13:49:24 17 inspection where MDR is brought up.

13:49:27 18 Q. Hold on. On that 2009 facility

13:49:30 19 inspection --

13:49:31 20 A. Right. The -- the 2010 warning letter.

13:49:33 21 Q. Right. And those are reports about burns;

22 right?

13:49:36 23 A. It -- it ended up being about burns, yeah.

13:49:38 24 But --

13:49:38 25 Q. Nothing about that MDR is about airborne

13:49:41 1 contamination.

13:49:42 2 A. No. That came later.

13:49:43 3 Q. Okay. In other words, the inspection that
13:49:47 4 Dr. David talks about in his report has no relation to
13:49:53 5 MD -- failure of MDR reporting or warning letters
13:49:57 6 relating to airborne contamination.

13:49:59 7 A. Well it doesn't in -- in -- in that the FDA
13:50:02 8 inspector evaluated 3M's medical device reporting
13:50:09 9 procedures, their thought process and their conduct,
13:50:13 10 so --

13:50:15 11 Q. What --

13:50:16 12 A. So -- so that's -- and -- and that was --

13:50:18 13 And that seemed to be fine according to the
13:50:23 14 FDA. It was -- it was certain individual reports as I
13:50:24 15 recall.

13:50:24 16 Q. What if any opinions did Dr. David express
13:50:27 17 regarding MDR reporting in connection with that 2009
13:50:31 18 inspection that you take issue with?

13:50:32 19 A. Well what I'm saying is that he mentioned
13:50:35 20 the -- the warning letter and I think within the
13:50:40 21 context of the troublesome conduct of the company, if
13:50:44 22 I'm not mistaken, so I thought it necessary to address
13:50:51 23 that. And, you know, due to your emphasis,
13:50:56 24 plaintiffs' emphasis on those litigation-based
13:51:01 25 reports, you know, that that seemed obvious I should

13:51:04 1 address it.

13:51:08 2 Q. You were retained to provide a -- a rebuttal
13:51:13 3 opinion report, rebuttal opinion testimony; correct?

13:51:16 4 A. Once I -- well --

13:51:18 5 MS. EATON: Object to the form of the
13:51:20 6 question.

13:51:20 7 A. In the MDL?

13:51:22 8 Q. Correct.

13:51:23 9 A. Yeah. I'm just wondering about the timing
13:51:26 10 of Dr. David's report. I think that's the case. The
13:51:28 11 reason I paused is because in Walton and Johnson, of
13:51:32 12 course, I didn't -- Dr. David had a report there, too,
13:51:36 13 but they came along later. In this case I think I
13:51:40 14 had -- I might be incorrect -- had Dr. David's report
13:51:43 15 first.

13:51:47 16 Q. Well what I'm trying to understand is
13:51:49 17 specifically in this case, this report right there,
13:51:53 18 that's -- you've been retained to provide rebuttal
13:51:55 19 testimony, rebuttal opinions in that report.

13:51:58 20 A. Yes. Yes.

13:51:58 21 Q. Okay. You were not retained to offer
13:52:02 22 broad-based testimony generally about the Bair Hugger.

13:52:06 23 MS. EATON: Object to the form of the
13:52:08 24 question.

13:52:09 25 A. Well I -- I --

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13:52:10 1 In my evaluation of the complaint and in the
13:52:14 2 context of how I evaluate devices, my opinions -- my
13:52:21 3 foundation for the appropriateness of the device from
13:52:25 4 a regulatory position must include an analysis of its
13:52:28 5 regulatory history and whether or not it's appropriate
13:52:32 6 or inappropriate.

13:52:34 7 Q. And that's completely independent whether or
13:52:35 8 not any given opinions are provided by plaintiffs'
13:52:37 9 experts.

13:52:39 10 A. Right. But we know, of course, Dr. David
13:52:41 11 did impugn the 510(k) process in his report.

13:52:44 12 Q. Sure. Sure. And we know there's plenty of
13:52:47 13 opinions about the 510(k) process and plenty of
13:52:50 14 opinions in your report addressing what Dr. David has
13:52:52 15 to say about the 510(k) process; correct?

13:52:55 16 A. Right.

13:52:55 17 Q. Okay. That is different from the opinions
13:52:57 18 you have that are not in any way connected with Dr.
13:53:00 19 David's report.

13:53:01 20 MS. EATON: Object to the form of the
13:53:02 21 question.

13:53:02 22 A. Well -- yes. In regard to the litigation-
13:53:08 23 based MDR reporting, my opinion is based on 510(k)s,
13:53:12 24 upon -- you know, I'll call them the front-end
13:53:15 25 opinions in my report are all foundational in regard

13:53:19 1 to addressing his opinions on 5 -- on the 510(k)

13:53:22 2 process.

13:53:22 3 Q. Okay. All right. Can you flip to 75 in

13:53:46 4 your report for me. All right. And you see here we

13:53:52 5 have opinion number nine; right?

13:53:54 6 A. Yes.

13:53:54 7 Q. And that opinion is about warning letters

13:53:57 8 that were sent in 2010; correct?

13:53:58 9 A. Correct.

13:54:01 10 Q. It's a warning letter you sent.

13:54:01 11 A. Under my signature, yes.

13:54:02 12 Q. Correct. Is there a distinction there?

13:54:05 13 A. Well I mean that I sent. Well, you know --

13:54:09 14 Yeah. I signed it, yes. Do I -- do I send

13:54:14 15 it? Well --

13:54:14 16 Q. You stand by what was said in the letter

13:54:14 17 though; right?

13:54:15 18 A. Of course I do.

13:54:16 19 Q. And that's --

13:54:17 20 I mean when it's under your signature,

13:54:18 21 you're responsible for what's in that letter.

13:54:20 22 A. Well it's my signature. It's FDA's advisory

13:54:23 23 action. I'm an agent of FDA in this instance.

13:54:25 24 Q. Okay. Now this opinion regards --

13:54:32 25 Let's just read the opinion out. "It is my

13:54:34 1 opinion that a 2010 Warning Letter from FDA to
13:54:37 2 Arizant, Incorporated did not result in any
13:54:41 3 observation regarding MDRs for complaints of infection
13:54:44 4 and the findings in the letter which were quickly
13:54:46 5 resolved does not undermine the reasonable assurance
13:54:50 6 of safety and effectiveness of the Bair Hugger."

13:54:52 7 What plaintiff opinion, if any, does this
13:54:55 8 rebut?

13:54:58 9 A. Well Dr. David --

13:55:00 10 Q. What opinion does Dr. David have --

13:55:04 11 A. -- referred to that warning letter.

13:55:04 12 Q. Okay. He referred to the warning letter.

13:55:05 13 A. Correct.

13:55:05 14 Q. What was his opinion about the warning
13:55:07 15 letter?

13:55:07 16 A. Well I can't -- I can't say it word for
13:55:11 17 word. I guess we'd have to look at that. But --

13:55:14 18 Q. Okay.

13:55:16 19 A. -- let me see where -- if and where I refer
13:55:20 20 to it.

13:55:31 21 Perhaps I don't, but --

13:55:32 22 Q. Well the problem I'm having, Mr. Ulatowski,
13:55:34 23 is -- is I'm word-searching as best I can through Mr.
13:55:37 24 David -- Dr. David's report, maybe we can take a break
13:55:40 25 at some time and go through it, but I'm not finding

13:55:43 1 any mention of a warning letter in Dr. David's report.

13:55:46 2 A. Well maybe I'm -- maybe I'm incorrect there.

13:55:48 3 Q. Okay. So this might be one of those
13:55:51 4 opinions that's more addressed to the allegations in
13:55:54 5 plaintiffs' complaint.

13:55:55 6 A. Perhaps.

13:55:55 7 Q. Okay. I want to go back to a discussion we
13:55:59 8 had a little bit earlier, and we had a discussion --

13:56:02 9 A. Can we -- excuse me.

13:56:03 10 Q. Sure.

13:56:04 11 A. If I --

13:56:07 12 I mean I do say, "This inspection is one of
13:56:08 13 the regulatory events Dr. David finds to be
13:56:11 14 troubling."

13:56:11 15 Q. Sure. The inspection is absolutely
13:56:13 16 discussed in Dr. David's report; isn't it? Yeah,
13:56:16 17 there's -- there's talk about the -- the visit for
13:56:18 18 discussion of airborne contamination issues.

13:56:20 19 A. Correct.

13:56:21 20 Q. Right. And then I think you also remember
13:56:23 21 there's some discussion about what may or may not have
13:56:25 22 been said about the filter.

13:56:26 23 A. Yes.

13:56:27 24 Q. Okay. There's no discussion about warning
13:56:29 25 letters for burns, though; is there?

13:56:32 1 A. No discussion of warning --

13:56:33 2 No. No. It's the visit, it's the

13:56:35 3 examination by --

13:56:36 4 But, you know, to me it's all part and

13:56:40 5 parcel of the same thing, the inspection, the

13:56:41 6 observations, the outcome.

13:56:42 7 Q. Okay. I want to talk to you a little bit

13:56:50 8 earlier when we spoke about the process by which you

13:56:55 9 examined conflicts before you take on litigation. You

13:56:58 10 remember we had that discussion this morning?

13:57:00 11 A. Yes.

13:57:00 12 Q. Okay. And part of that discussion is we

13:57:02 13 were talking about a hypothetical FDA employee who

13:57:07 14 might have a conflict if they had some direct personal

13:57:12 15 involvement in the regulation of the product they're

13:57:15 16 testifying about, and specifically, for instance, say,

13:57:17 17 an employee who approved a 510(k) and then was going

13:57:21 18 to give testimony about whether that was proper or

13:57:24 19 not. That could raise an issue that is not present in

13:57:27 20 this case; correct?

13:57:28 21 A. Yes.

13:57:29 22 Q. Okay. And that's because you had no

13:57:31 23 personal direct involvement in approving any of these

13:57:34 24 510(k)s we've been talking about today.

13:57:36 25 A. Yes. And clearing, yeah.

13:57:38 1 Q. And the Bair Hugger did not come through
13:57:40 2 your office for 510(k) clearance.

13:57:42 3 A. My division, no.

13:57:44 4 Q. In -- in your division.

13:57:45 5 So I think the other thing you've testified
13:57:47 6 to me is unlike in a case where you might have a
13:57:49 7 conflict, there's not a letter in this case with your
13:57:51 8 name on it that says clearance for a Bair Hugger under
13:57:55 9 510(k).

13:57:55 10 A. Correct.

13:57:56 11 Q. Okay. Now when a 510(k) is granted --

13:58:13 12 When it's cleared would be the correct term;
13:58:14 13 right?

13:58:14 14 A. Correct.

13:58:15 15 Q. I keep messing that up. And I'm going to
13:58:16 16 get it. You know, by the end of this litigation, I
13:58:18 17 think I'm going to start saying "clearance" every
13:58:21 18 time.

13:58:21 19 But when a 510(k) product is cleared, the --
13:58:23 20 the manufacturer is notified; correct?

13:58:25 21 A. There's an order issued by FDA and -- you
13:58:29 22 know, by letter, yes.

13:58:30 23 Q. And then the letter is sent letting them
13:58:33 24 know that the -- we've -- we've determined substantial
13:58:37 25 equivalency and you're now cleared to market the

13:58:40 1 product.

13:58:40 2 A. Correct.

13:58:41 3 Q. And also provides them with some other
13:58:44 4 general information about other things they need to be
13:58:46 5 aware of to comply with certain controls and
13:58:49 6 regulations.

13:58:52 7 A. Correct.

13:58:52 8 Q. And that they have ongoing obligations even
13:58:52 9 after the clearance is granted.

13:58:53 10 A. Correct.

13:58:54 11 Q. All right. And then that letter is issued
13:58:56 12 by whatever controlling division has performed the
13:58:59 13 review and -- and assessed the okay on the 510(k)
13:59:02 14 clearance.

13:59:03 15 A. Right. It's a form letter that's used by
13:59:05 16 every -- every division. It's changed over time.

13:59:08 17 Q. Okay. I want to show you one of those
13:59:10 18 letters so we can talk about it, about what's
13:59:12 19 contained in those kind of letters.

13:59:19 20 MR. BANKSTON: Can I have that marked.

13:59:29 21 (Ulatowski Exhibit 5 was marked for
13:59:30 22 identification.)

13:59:31 23 BY MR. BANKSTON:

13:59:31 24 Q. All right, Mr. Ulatowski, we're looking at a
13:59:33 25 document here. Do you see here at the top it says

13:59:35 1 April 30th, 1998?

13:59:36 2 A. Yes.

13:59:37 3 Q. It's addressed to Scott D. Augustine, M.D.

13:59:39 4 at Augustine Medical; correct?

13:59:40 5 A. Correct.

13:59:41 6 Q. The product is a Bair Hugger Fluid Warmer,

13:59:44 7 Class II.

13:59:44 8 A. Yes.

13:59:45 9 Q. Right. And this product code's BSB and this

13:59:52 10 was done in February of 1998; correct?

13:59:52 11 A. Correct.

13:59:53 12 Q. Okay. So now we have this kind of letter

13:59:55 13 we've just been talking about that approved the 510(k)

13:59:57 14 and says that "We have reviewed your 510(k)

14:00:00 15 notification of intent to market the device referenced

14:00:03 16 above and we have determined that the device is

14:00:04 17 substantially equivalent...to devices marketed in

14:00:06 18 interstate commerce prior to 20 -- May 28th, 1976."

14:00:11 19 A. Correct.

14:00:12 20 Q. Correct?

14:00:12 21 MS. EATON: Object to the form of the

14:00:15 22 question.

14:00:15 23 MR. BANKSTON: Yeah. We'll -- we'll just

14:00:15 24 add for the record that we omitted a parenthetical;

14:00:18 25 didn't we?

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14:00:18 1 MS. EATON: That's not my objection though.

14:00:19 2 MR. BANKSTON: Okay. What is your

14:00:22 3 objection?

14:00:22 4 MS. EATON: You equated this to the kind of

14:00:23 5 letter that the two of you have been discussing.

14:00:24 6 MR. BANKSTON: Okay.

14:00:25 7 Q. Mr. Ulatowski, you remember we just talked a

14:00:27 8 minute ago about the letters that were sent that said

14:00:30 9 here is your 510(k), it is substantially equivalent,

14:00:33 10 you're now allowed to market the device, here are some

14:00:37 11 more instructions?

14:00:37 12 A. Correct.

14:00:37 13 Q. That's this kind of letter.

14:00:40 14 A. Yes.

14:00:42 15 Q. Yes. Okay. So the next part of this says

14:00:42 16 the things we were talking about before about here are

14:00:45 17 some things you might need to pay attention to. Do

14:00:48 18 you agree with me there?

14:00:49 19 A. Yes.

14:00:49 20 Q. This is the approval letter for a Bair

14:00:51 21 Hugger product; correct?

14:00:52 22 A. For -- for the blood fluid warmer.

14:00:55 23 Q. Right. So --

14:00:56 24 A. It's one of the accessories, yeah.

14:00:59 25 Q. Right. Right. It's a Bair Hugger product.

14:01:00 1 MS. EATON: Object to the form of the
14:01:01 2 question.

14:01:01 3 A. It's -- it's one of the -- yes, one of the
14:01:03 4 devices used with the -- with the unit.

14:01:05 5 Q. Yes, exactly.

14:01:06 6 The device has several components to it;
14:01:08 7 doesn't it?

14:01:08 8 A. Correct.

14:01:08 9 Q. Right. It says --

14:01:10 10 In fact, I think what you could refer to as
14:01:11 11 a -- the company has referred to it on occasion as a
14:01:16 12 patient warming system.

14:01:17 13 A. Right. And this is one of the optional
14:01:19 14 accessories used specifically for the stated case,
14:01:22 15 blood fluid warming.

14:01:23 16 Q. Okay. So we have a -- a regulatory letter
14:01:25 17 here with an action by the FDA granting a 510(k)
14:01:30 18 approval to a Bair Hugger; correct?

14:01:31 19 MS. EATON: Object to the form of the
14:01:32 20 question.

14:01:33 21 A. To a blood fluid warmer.

14:01:36 22 Q. Okay. So we're going to make a distinction
14:01:38 23 here that a blood fluid warmer -- a Bair Hugger blood
14:01:42 24 fluid warmer is not a Bair Hugger product.

14:01:44 25 A. It's one of the Bair Hugger accessories, as

14:01:46 1 I said -- said already.

14:01:48 2 Q. Okay. Bair Hugger devices have been

14:01:53 3 submitted to the FDA for approval.

14:01:55 4 A. Well there's systems consisting of the unit,

14:01:59 5 of a hose, of optional equipment, blankets. A blood

14:02:04 6 fluid warmer is one of the optional elements that's

14:02:08 7 somewhat unique, and it's used with the Bair Hugger.

14:02:09 8 Q. Okay. So this letter granting approval had

14:02:15 9 to do with Dr. Augustine submitting a Bair Hugger

14:02:19 10 product to the FDA and the -- and the company

14:02:22 11 evaluating how it was used --

14:02:23 12 A. Uh-huh.

14:02:24 13 Q. -- and coming to a decision on it.

14:02:25 14 A. Uh-huh.

14:02:26 15 Q. Okay.

14:02:27 16 THE REPORTER: Your answer?

14:02:28 17 THE WITNESS: Yes, yes.

14:02:29 18 Q. This is a letter that you signed.

14:02:30 19 A. Correct.

14:02:33 20 Q. Okay. This comes out of the Center for

14:02:33 21 Device Evaluation.

14:02:35 22 A. Yes. Office.

14:02:37 23 Q. Office. Excuse me. Comes out of the Office

14:02:37 24 of Device Evaluation.

14:02:39 25 A. Right.

14:02:39 1 Q. Comes from the Center for Devices and
14:02:41 2 Radiological Health.

14:02:43 3 A. Correct.

14:02:44 4 Q. That's -- that's your center.

14:02:45 5 A. Right.

14:02:46 6 Q. Okay. So you will agree with me that you
14:02:48 7 had personal involvement in granting a 510(k)
14:02:50 8 clearance to a Bair Hugger product.

14:02:54 9 A. Right. A Bair Hugger accessory used for
14:02:55 10 blood fluid warming, evidently.

14:02:57 11 Q. Evidently so.

14:03:00 12 Have you seen this document before?

14:03:11 13 A. No, I didn't recollect this, but I'm not
14:03:13 14 surprised because my division handled IV solution
14:03:20 15 containers, perhaps blood -- blood containers, so I'm
14:03:27 16 not surprised by this. I -- it --

14:03:29 17 I didn't think about it, but I'm not
14:03:31 18 surprised to see this. And again, it's not the device
14:03:34 19 that's really subject of this litigation, you know,
14:03:37 20 it's not the -- the air-blowing device with the hose
14:03:41 21 and the blankets.

14:03:41 22 Q. Okay. So I guess that would be the
14:03:44 23 qualification to the answers you gave this morning.

14:03:47 24 A. Well becoming aware of this, it's -- my
14:03:51 25 answer is, well, so what? You know, this is not the

14:03:54 1 focus of this particular litigation, this -- this

14:03:56 2 accessory. Is it?

14:03:58 3 Q. So --

14:03:58 4 A. It is not.

14:03:59 5 Q. -- when I asked the question this morning,

14:04:01 6 there's not a letter that says Bair Hugger on it that

14:04:04 7 has Tim Ulatowski's name on it, that was not a correct

14:04:07 8 answer.

14:04:07 9 A. Well I was assuming the air-blowing device

14:04:10 10 with the blankets and the blower.

14:04:11 11 Q. Well we were talking about whether this

14:04:13 12 creates a conflict between you and your client.

14:04:16 13 That's -- that's one of your client's devices; right?

14:04:18 14 A. Yes, it is.

14:04:20 15 Q. It's a Bair Hugger device.

14:04:20 16 A. It's an accessory, yes, --

14:04:22 17 Q. Okay.

14:04:22 18 A. -- to the Bair Hugger.

14:04:24 19 MS. EATON: Let me just go back and object

14:04:26 20 to the form of the previous question.

14:04:27 21 MR. BANKSTON: Okay.

14:04:28 22 Q. You agree this creates a conflict between

14:04:32 23 you and your client; correct?

14:04:34 24 MS. EATON: Object to the form of the

14:04:35 25 question.

14:04:35 1 Actually, I withdraw my objection.

14:04:37 2 A. Absolutely not. This isn't even the topic
14:04:42 3 of this litigation.

14:04:44 4 Q. That's your interpretation today; correct?

14:04:47 5 A. I've given you my answer.

14:04:49 6 Q. Have you talked --

14:04:51 7 Have you asked the FDA Ethics Office about
14:04:53 8 that?

14:04:53 9 A. No. I won't burden them with this
14:04:57 10 triviality.

14:04:57 11 Q. Avoiding conflicts of interest, --

14:05:01 12 A. We've already --

14:05:02 13 Q. -- that's not trivial; is it?

14:05:03 14 A. Excuse me. They've already opined on my
14:05:05 15 participation in litigation, even in 510(k)s where
14:05:08 16 I've been involved, allowing me to testify, provided,
14:05:11 17 as I stated early on, the source of information upon
14:05:15 18 which I'm opining is the litigation production,
14:05:19 19 information provided, and I'm not relying on
14:05:22 20 information known to me and not known otherwise to
14:05:26 21 anyone else about what I know from FDA.

14:05:29 22 Q. Let me make sure I have this totally clear
14:05:31 23 for the record. You are saying that you believe it is
14:05:34 24 ethically appropriate for you to be involved in a
14:05:38 25 piece of litigation where you had direct personal

14:05:40 1 involvement in regulating the product line being
14:05:43 2 litigated.

14:05:48 3 A. Yes. I've done so before, and I have not
14:05:50 4 been prevented from doing so upon the opinion of the
14:05:53 5 Ethics Office. And again, I know it may be a big deal
14:05:59 6 to you, but this is even -- not even the subject of
14:06:02 7 this litigation for this particular device.

14:06:04 8 Q. Well let's -- let's just go ahead and focus
14:06:07 9 like a laser in on that, then, not just the device but
14:06:10 10 the issues we're talking about today.

14:06:11 11 When it comes to the allegations of airborne
14:06:14 12 contamination, did you have any personal involvement
14:06:15 13 at all at the FDA to reviewing those allegations?

14:06:19 14 A. No.

14:06:20 15 Q. Okay.

14:06:20 16 A. Well let me take that back. You know, it
14:06:24 17 was the subject of evaluation of FDA inspection, but I
14:06:29 18 believe that came along after I had departed from FDA.

14:06:31 19 Q. What I guess I'm asking you is: Have you
14:06:34 20 been involved in written communications between, say,
14:06:37 21 either Augustine or with your current client about
14:06:40 22 airborne contamination issues while you were
14:06:43 23 responsible for compliance at the FDA?

14:06:46 24 A. Airborne compliance --

14:06:48 25 Airborne contamination generally or

14:06:49 1 specifically?

14:06:49 2 Q. No, the --

14:06:50 3 I mean let's just break it down to the very,
14:06:53 4 very laser-like, specific allegations in this case.

14:06:56 5 All right? You understand, for instance, we talk
14:06:57 6 about the Augustine MedWatch reports --

14:06:59 7 A. Uh-huh.

14:07:00 8 Q. -- and the allegations --

14:07:01 9 A. Yes.

14:07:02 10 Q. -- made within them; correct?

14:07:03 11 A. Yes.

14:07:03 12 Q. And they concern airborne contamination.

14:07:06 13 A. That's one aspect, yes.

14:07:07 14 Q. And you --

14:07:08 15 So you understand generally what I mean when
14:07:10 16 I say the allegations made by Dr. Augustine.

14:07:13 17 A. Yes.

14:07:14 18 Q. Okay. And from what I understand your
14:07:16 19 testimony is, you had no direct involvement at the FDA
14:07:20 20 or any written communications with Dr. Augustine or
14:07:23 21 with your current client relating to those allegations
14:07:28 22 while you were doing enforcement for this product
14:07:31 23 line.

14:07:32 24 A. Well I know there was a warning letter to
14:07:34 25 Dr. Augustine on his Blowing Air Is Risk -- or

14:07:40 1 something related to some device. I'm not sure if
14:07:43 2 that's particularly relevant here, but I would have to
14:07:45 3 look at that.

14:07:46 4 Q. Did you have something to do with that?

14:07:48 5 A. I'd have to look at the dates of that. It's
14:07:49 6 in my report.

14:07:50 7 Q. Okay. That's all there is. That's the
14:07:53 8 extent of your -- your personal involvement or
14:07:54 9 communications on this issue.

14:07:56 10 MS. EATON: Object to the form of the
14:07:57 11 question.

14:07:57 12 A. As far I recall.

14:07:58 13 Q. Okay. And that's something that would be
14:07:59 14 important for you to check into and look into before
14:08:01 15 you took this case.

14:08:04 16 A. Well to the degree I can recall, because I
14:08:05 17 had no FDA records. I took none with me. I have no
14:08:09 18 documents whatsoever. The best I can do is recollect
14:08:12 19 any involvement or through any production in any
14:08:14 20 litigation where that's --

14:08:17 21 Q. Very good point.

14:08:18 22 A. -- evident.

14:08:29 23 (Ulatowski Exhibit 6 was marked for
24 identification.)

25 BY MR. BANKSTON:

1 Q. Mr. Ulatowski, this is a letter sent by
14:08:35 2 Arizant Healthcare on August 16, 2010. This is not a
14:08:39 3 document you've relied on in this case; correct?

14:08:45 4 A. Hang on just a moment here.

14:08:47 5 Q. Uh-huh.

14:08:59 6 A. I don't -- I don't think so, but --

14:09:01 7 I don't believe I was at that point in time
14:09:04 8 technically the director of the Office of Compliance
14:09:09 9 at that point in time, so I don't think I have any
14:09:09 10 knowledge of this letter.

14:09:11 11 Q. Okay. You know, I mean you don't remember
14:09:13 12 it, I'm assuming. This is --

14:09:15 13 A. Right.

14:09:15 14 Q. -- seven years ago, something like that.

14:09:17 15 A. Right. Well I don't remember, but -- but
14:09:20 16 let me explain. I re -- I retired from FDA in January
14:09:23 17 of 2011. In approximately July or so I assumed a
14:09:30 18 temporary position as senior advisor for enforcement
14:09:35 19 to the commissioner and to the center director, and I
14:09:40 20 delegated my responsibilities as director of
14:09:44 21 compliance to another person during that period of
14:09:46 22 time. So I don't think I know about this letter, to
14:09:48 23 tell you the truth.

14:09:49 24 Q. Okay. During the time you were director of
14:09:54 25 the Office of Compliance for the Centers of Devices

14:09:56 1 and Radiological Health, you had confined -- you had
14:10:00 2 enforcement authority over the Bair Hugger line.

14:10:04 3 A. Yes.

14:10:04 4 Q. This letter was sent to you; correct?

14:10:06 5 MS. EATON: Object to the form of the
14:10:07 6 question.

14:10:08 7 A. It was cc'd to me, yes.

14:10:09 8 Q. You received this letter.

14:10:12 9 A. You know, I don't know if I received it
14:10:15 10 or --

14:10:15 11 It was directed to the acting director of
14:10:17 12 compliance.

14:10:18 13 Q. How would you have any idea that this was
14:10:22 14 directed to the acting director?

14:10:23 15 A. Because that would be the case.

14:10:25 16 Q. Right. So I mean other than the main
14:10:28 17 recipient; right? You understand it's directly
14:10:31 18 addressed to him.

14:10:31 19 A. Right.

14:10:32 20 Q. Okay. So it's cc'd to you.

14:10:34 21 A. Correct.

14:10:35 22 Q. Right. So it's not like your copy is then
14:10:37 23 going to be taken and given to him; is it?

14:10:39 24 A. No. What I'm saying is my copy would have
14:10:42 25 been given to the acting director of compliance.

14:10:43 1 Q. That's this person.

14:10:44 2 A. No, no. No, no. This is a different

14:10:47 3 office.

14:10:47 4 Q. Oh, he's in a different office. He's in --

14:10:49 5 A. Right.

14:10:51 6 Q. -- Postmarket Surveillance.

14:10:51 7 A. Right.

14:10:53 8 Q. So you --

14:10:53 9 There would be a different acting director

14:10:53 10 for compliance --

14:10:54 11 A. Right.

14:10:55 12 Q. -- and that when you got this letter --

14:10:56 13 A. I was out of the loop already.

14:10:58 14 Q. And may have, either your or someone else

14:11:02 15 you're saying, forwarded it to that person.

14:11:02 16 A. Right.

14:11:03 17 Q. You have no specific memory of any of this.

14:11:05 18 A. No.

14:11:05 19 Q. The only thing that we can say for any

14:11:07 20 certainty at all is that your current client sent you

14:11:10 21 a letter on this date; right?

14:11:12 22 A. Sent --

14:11:12 23 MS. EATON: Object to the form of the

14:11:13 24 question.

14:11:14 25 A. Sent Mr. Douglas, with a letter on which I

14:11:16 1 was cc'd.

14:11:17 2 Q. Right. And I mean you don't --

14:11:19 3 I don't think there's a meaningful

14:11:20 4 distinction between that. Do you?

14:11:21 5 A. Well if a letter came to the director of

14:11:24 6 compliance in my office --

14:11:25 7 In fact, I wasn't even residing in my -- in

14:11:29 8 my office at that point in time, so it would have been

14:11:31 9 forwarded to the acting director of compliance.

14:11:32 10 Q. Okay. This is a letter that was sent to you

14:11:35 11 that outlines a discussion of the very allegations

14:11:39 12 we've been discussing today; correct?

14:11:41 13 A. Well, you know, of course this is news to

14:11:43 14 me, but okay.

14:11:45 15 Q. That's true; right?

14:11:47 16 MS. EATON: Object to the form of the

14:11:48 17 question.

14:11:49 18 A. What's the question?

14:11:49 19 Q. The question was: This is a letter that is

14:11:52 20 addressed with your address on it that was sent to you

14:11:57 21 that discusses the airborne contamination issues and

14:12:01 22 allegations that we've been discussing today.

14:12:06 23 A. Well I have to read it first of all. Let me

14:12:08 24 read it, --

14:12:08 25 Q. Sure.

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14:12:09 1 A. -- see what this is all about, because this
14:12:11 2 is news to me.

14:12:43 3 Okay, I've read it.

14:12:45 4 Q. Okay. Your answer?

14:12:46 5 A. Never saw it before.

14:12:47 6 Q. That's not the question, sir.

14:12:49 7 A. What's the question?

14:12:49 8 Q. The question for the third time is: This is
14:12:51 9 a letter addressed with your name on it, your address,
14:12:55 10 that discusses the allegations of airborne
14:12:58 11 contamination that we've been discussing today.

14:13:00 12 A. Yes. My address is on here.

14:13:01 13 Q. Uh-huh.

14:13:02 14 A. I never received it. I have no knowledge of
14:13:07 15 it.

14:13:07 16 Q. You -- well let's -- let's back up. You
14:13:07 17 don't have any independent knowledge about whether you
14:13:09 18 actually put hands on this letter seven years ago; do
14:13:12 19 you?

14:13:12 20 A. It's unlikely I did because of the reasons I
14:13:14 21 said already.

14:13:14 22 Q. All right. Prior to this letter, you had
14:13:18 23 been directly sent MedWatch reports relating to these
14:13:21 24 issues; correct?

14:13:22 25 A. No, I wouldn't have received them directly.

14:13:24 1 Q. You deny that you were directly sent
14:13:26 2 MedWatch reports by Dr. Augustine.

14:13:27 3 A. I don't know if I was directly sent, but FDA
14:13:30 4 may have been sent MedWatch reports.

14:13:33 5 Q. And at that time when you were in the Office
14:13:34 6 of Compliance, if you had a MedWatch report relating
14:13:36 7 to the Bair Hugger line, you had the authority to take
14:13:39 8 compliance action; correct?

14:13:39 9 A. If I had --
14:13:43 10 Again, say again.

14:13:44 11 Q. Sure. While you were in the Office of
14:13:46 12 Compliance, if it came into your possession a MedWatch
14:13:49 13 report that alleged some sort of problem with a
14:13:53 14 device, you had it within your authority to take
14:13:56 15 regulatory compliance action on that line.

14:14:07 16 MS. EATON: Object to the form of that
14:14:08 17 question.

14:14:09 18 A. MedWatch reports in and of themselves do not
14:14:13 19 precipitate enforcement action.

14:14:15 20 Q. Okay. In your job as enforcement director
14:14:19 21 or director of compliance --

14:14:19 22 A. Director of compliance.

14:14:20 23 Q. -- director of compliance in your division,
14:14:23 24 you reviewed MedWatch reports.

14:14:24 25 A. I did. I wasn't the primary evaluator of

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14:14:27 1 MedWatch reports. And let me explain. The MedWatch
14:14:30 2 reports are sent to another office, Division of
14:14:33 3 Postmarket Surveillance. That office evaluates the
14:14:36 4 MedWatch reports. If there's some problem with --
14:14:40 5 with the MedWatch reports that's identified by that
14:14:43 6 office, they may forward a -- a notice to the Office
14:14:49 7 of Compliance that something needs to be looked into
14:14:52 8 or whatever. So it's that office's responsibility for
14:14:55 9 evaluating the MedWatch reports.

14:14:57 10 Q. Okay. So what -- what --

14:15:01 11 Towards what end would you review a MedWatch
14:15:03 12 report?

14:15:03 13 A. If there's been, as I said, a -- a forwarded
14:15:09 14 recommendation for potential enforcement action by
14:15:13 15 that office I just spoke of, if during an inspection
14:15:16 16 there'd been evidence of non-compliance of a nature
14:15:22 17 that -- where enforcement action is indicated, I would
14:15:25 18 be involved in that. So those are two examples.

14:15:29 19 Q. Okay. In other words, during the time at
14:15:32 20 which Augustine submitted his first MedWatch report,
14:15:37 21 circa 2009, that would be a time in which you were in
14:15:40 22 the Office of Compliance; correct?

14:15:41 23 A. Yes. Yes.

14:15:49 24 Q. Did we --

14:15:50 25 I don't know if I maybe asked you this or

14:15:52 1 not. This is not a document you reviewed before this
14:15:54 2 litigation?

14:15:55 3 A. It looks new to me.

14:15:58 4 Q. Okay. And it's not one of the ones that
14:15:58 5 would be cited in your report.

14:16:01 6 MS. EATON: I would simply ask that we check
14:16:03 7 that.

14:16:03 8 A. Perhaps. Perhaps. I just don't recognize
14:16:06 9 it.

14:16:06 10 Q. Right. That would be really surprising if
14:16:08 11 it was.

14:16:12 12 You made no efforts --

14:16:13 13 A. Well excuse me. If -- if it was, you know,
14:16:16 14 I had no participation in it as -- for the reasons I
14:16:20 15 stated.

14:16:20 16 Q. You don't --

14:16:21 17 At least that's what you can testify to
14:16:23 18 today seven years later.

14:16:24 19 A. Well it's just the timing is -- is my basis,
14:16:27 20 because at that point in time I was out of the loop in
14:16:29 21 compliance. I was -- I was assigned to other duties
14:16:32 22 at that point.

14:16:32 23 Q. You cannot testify to me today that you were
14:16:34 24 not privy to this information.

14:16:36 25 A. It's unlikely I was because of the

14:16:38 1 timeframe.

14:16:40 2 Q. That's not an answer to the question. You
14:16:40 3 understand that.

14:16:41 4 A. To the best of my knowledge, based upon the
14:16:44 5 facts here, I can say with -- with a high degree of
14:16:49 6 certainty I was out of the loop.

14:16:50 7 Q. Okay. When you got involved in this case
14:16:55 8 and you started going through documents, did you ever
14:16:59 9 think to look to see if you had ever been personally
14:17:02 10 involved in this case by looking through the documents
14:17:04 11 that are produced in this lawsuit?

14:17:06 12 A. Well that's something I look at. I look at
14:17:08 13 the 510(k)s, for example. I look at any particular
14:17:15 14 evidence otherwise that seems to be immediately
14:17:18 15 apparent, you know. So -- so I do some diligence --
14:17:22 16 some degree of diligence at the front end. And of
14:17:25 17 course if there is some relationship, then typically
14:17:28 18 the lawyers know that connection coming in at the
14:17:31 19 front end, or people in the company know that
14:17:34 20 connection at the front end.

14:17:35 21 Q. Uh-huh.

14:17:36 22 A. And, you know, I -- I was unaware.

14:17:42 23 Q. So there was never any time that you, for
14:17:46 24 instance, searched the document production for your
14:17:47 25 own name.

14:17:53 1 A. Well it would have been difficult to do a
14:17:55 2 word search on all the documents the way they were
14:17:58 3 provided to me, but -- because some of the f -- pdf's
14:18:01 4 were not word-searchable.

14:18:03 5 Q. I actually --

14:18:04 6 What I really meant was not just the
14:18:08 7 documents you provided to you, but the total sum of
14:18:10 8 litigation documents in this case. Do you know if a
14:18:11 9 word search had been perverted -- or performed for
14:18:14 10 "Ulatowski" on those documents?

14:18:15 11 A. I have no knowledge of that.

14:18:15 12 Q. Okay. That's not something you did.

14:18:17 13 A. No, it's not something I did.

14:18:19 14 Q. Not something you requested.

14:18:20 15 A. Not something I requested.

14:18:21 16 Q. And I take it --

14:18:22 17 A. And the reason being, since these were
14:18:26 18 regulated, except for the fluid warmer, in a different
14:18:29 19 division for 510(k) purposes, I -- I certainly would
14:18:31 20 not be in that loop. For compliance, I was aware of
14:18:35 21 the warning letter, so I was aware of that. Other
14:18:38 22 than that, you know --

14:18:41 23 Q. What I think we can say, then, is before you
14:18:44 24 became a retained expert, before you took on this
14:18:49 25 client, before you formed any relationship with them

14:18:52 1 and signed any papers, you did not make a request to
14:18:56 2 these lawyers or the company, "Please provide me with
14:18:59 3 any indication of any of my involvement in the events
14:19:02 4 of this case."

14:19:03 5 A. I don't recall that specific request. But
14:19:08 6 typically that's revealed early on anyhow.

14:19:10 7 Q. Typically it is.

14:19:11 8 A. Yes.

14:19:12 9 Q. It was not in this case.

14:19:13 10 MS. EATON: Object to you getting into
14:19:15 11 discussions that he may have had with lawyers.

14:19:16 12 MR. BANKSTON: I'll agree --

14:19:17 13 MS. EATON: You know that that's improper.

14:19:19 14 MR. BANKSTON: And I asked before he ever
14:19:21 15 formed a relationship, before he ever signed a piece
14:19:24 16 of paper --

17 MS. EATON: And I --

14:19:25 18 MR. BANKSTON: -- and he was still just a
14:19:27 19 former FDA employee, not a retained expert.

14:19:31 20 MS. EATON: I'm talking about the follow-up
14:19:32 21 that he's speaking of that it's revealed early on.

14:19:36 22 MS. BANKSTON: What -- what was that about
14:19:38 23 communications? I'm trying to figure out what that
24 was --

14:19:38 25 How did that implicate communications?

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14:19:38 1 MS. EATON: I am asking that we please not
14:19:40 2 talk about any discussions he may have had with
14:19:43 3 lawyers. As long as you're not asking about that, I
14:19:45 4 want --

14:19:45 5 I heard your question --

14:19:46 6 MR. BANKSTON: All right.

14:19:47 7 MS. EATON: -- to perhaps implicate that,
14:19:49 8 and that's why I said what I said. If you're not
14:19:52 9 asking that, that's fine.

14:19:53 10 MR. BANKSTON: No, that's what I was asking
14:19:55 11 is the basis, and there's nothing in that question
14:19:56 12 that you can identify to me about communications. Or
14:19:59 13 is there, because I --

14:20:01 14 MS. EATON: Well if you would like me to
14:20:01 15 scroll back, I can look. But I'm simply telling
14:20:02 16 you --

14:20:02 17 MR. BANKSTON: I'm going to have to ask a
14:20:04 18 new question anyway.

14:20:04 19 MS. EATON: Yeah, that's fine. I'm simply
14:20:06 20 telling you what my concern was.

14:20:07 21 MR. BANKSTON: Okay. Yeah. That makes us
14:20:10 22 ask a new question.

14:20:10 23 MS. EATON: Because I have a legitimate
14:20:11 24 concern that I was protecting.

14:20:12 25 Q. So we know -- okay.

14:20:14 1 So we have in this case been discussing
14:20:18 2 whether you had any personal involvement relating to
14:20:22 3 the product, and one of the things I think was
14:20:26 4 mentioned early was this warning letter, this advisory
14:20:30 5 action; right?

14:20:32 6 A. 2010?

14:20:33 7 Q. Yes. Okay. So in your role as compliance,
14:20:39 8 you had a direct personal involvement in the
14:20:41 9 regulation and advising of compliance to the product
14:20:47 10 the Bair Hugger.

14:20:48 11 A. And every other medical device manufactured.
14:20:50 12 So am I excluded from all litigation? I doubt it.

14:20:53 13 Q. Hmm.

14:20:54 14 A. I doubt it.

14:20:55 15 Q. Probably not.

14:20:56 16 A. Probably not.

14:20:57 17 Q. Probably not.

14:20:58 18 A. Yeah. Probably not. Right.

14:21:00 19 Q. No. Because apparently your testimony to me
14:21:03 20 today is that if you had direct personal involvement
14:21:06 21 in a compliance action, an enforcement action or an
14:21:09 22 approval or clearance action, that you think it is
14:21:12 23 fine for you to testify in that case.

14:21:14 24 MS. EATON: Object to the form of the
14:21:15 25 question.

14:21:16 1 A. I -- I sought Ethics Office input. They
14:21:19 2 provided their opinion. "Fine, go ahead, and here's
14:21:23 3 the provisions under which you can do so."

14:21:25 4 Q. Let's make it very clear for the record.
14:21:27 5 When you speak of your discussions with the Ethics
14:21:30 6 Offices at the FDA, you have never once discussed
14:21:33 7 anything relating to 3M, Arizant, or the Bair Hugger.

14:21:37 8 A. No. Makes no matter because it's the same
14:21:40 9 situation.

14:21:42 10 Q. Were you involved in any FDA approvals --
14:21:54 11 excuse me, the --

14:21:55 12 Were you involved in any of the 510(k)
14:21:57 13 clearances for I-Flow? Did you sign any of those
14:22:01 14 letters?

14:22:01 15 A. Yes.

14:22:05 16 Q. Okay. Let's talk a little bit about
14:22:07 17 warnings in labels. You want to go to page 66 of your
14:22:10 18 report for me?

14:22:11 19 A. Okay.

14:22:18 20 Q. Let's first talk about the basic general
14:22:22 21 opinion that warnings and labels met regulatory
14:22:25 22 requirements and industry standards. All right?

14:22:26 23 A. That's what it says.

14:22:28 24 Q. And no basis to find it misbranded.

14:22:31 25 A. That's correct.

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14:22:31 1 Q. Okay. I want you to flip further into the
14:22:33 2 discussion of this to page 73.

14:22:35 3 A. Okay.

14:22:39 4 Q. All right. I want to direct your attention
14:23:02 5 to the final paragraph on page 73. Do you see there
14:23:07 6 it says, "According to the FDA" --

14:23:09 7 Or let me start that again so -- I want to
14:23:13 8 make sure we get this word perfect. "According to
14:23:15 9 FDA, a Warning in labeling may be appropriate if there
14:23:18 10 is reasonable evidence of an association of a serious
14:23:22 11 hazard with the use of the device." That's correct?

14:23:26 12 A. Correct. I reference that.

14:23:28 13 Q. All right. And that cites your footnote 132
14:23:33 14 is an FDA guidance document; correct?

14:23:33 15 A. Correct.

14:23:34 16 Q. These are known as Blue Book guidance;
14:23:37 17 correct?

14:23:37 18 A. Correct.

14:23:38 19 Q. Okay. And that cites an FDA website;
14:23:41 20 correct?

14:23:41 21 A. Correct.

14:23:42 22 Q. Okay. Now in your report you give four
14:23:45 23 reasons why a warning -- the lack of a warning was
14:23:49 24 appropriate, and I want to talk about those four
14:23:51 25 reasons.

14:23:51 1 A. Okay.

14:23:52 2 Q. And you understand that the first of your
14:23:54 3 reasons was that there were no MDR reports pertaining
14:23:57 4 to infections.

14:24:00 5 A. Correct, until Dr. Augustine-induced reports
14:24:04 6 began in 2015-'16.

14:24:06 7 Q. Okay. And you call that a paucity of MDR
14:24:10 8 reports pertaining to infections.

14:24:12 9 A. Correct.

14:24:12 10 Q. Okay. So is it your testimony that no
14:24:16 11 warnings need to be given until customers can prove
14:24:20 12 they're getting hurt?

14:24:20 13 MS. EATON: Object to the form of the
14:24:21 14 question.

14:24:22 15 A. No. There has to be --

14:24:24 16 That's not what I'm saying.

14:24:25 17 Q. I'm wondering why the existence or non-
14:24:28 18 existence of MDR reports of customers being able to
14:24:32 19 prove that they're hurt is relevant to whether a
14:24:36 20 warning should be given or not. Can you explain that
14:24:37 21 to me?

14:24:37 22 A. Well, you know, MDR reports are not proof
14:24:39 23 positive of -- of injury and causation.

14:24:42 24 Q. Absolutely.

14:24:42 25 A. Right?

14:24:43 1 Q. Sure.

14:24:43 2 A. So, you know, just to correct your statement
14:24:47 3 there.

14:24:48 4 Warnings are an element of labeling.

14:24:52 5 Warnings are essentially adverse effects that have
14:25:01 6 been -- company's been made aware of that are of
14:25:05 7 particular significance.

14:25:05 8 Q. Okay. So let's just go back, though, to MDR
14:25:09 9 reports.

14:25:10 10 A. Okay.

14:25:11 11 Q. There are situations where a company could
14:25:13 12 have MDR reports and have actually made MDR reports to
14:25:16 13 the FDA because there may have been a device injury,
14:25:19 14 not sure, doesn't look like it, but there may have
14:25:22 15 been, so they gave them the report, and simply because
14:25:25 16 there's been reports and they've gotten allegations,
14:25:27 17 that doesn't necessarily mean they have to give a
14:25:29 18 warning; right?

14:25:30 19 A. Right. There has to be some assessment of
14:25:32 20 that, of the association, the reason -- reasonableness
14:25:36 21 of the report and the association.

14:25:38 22 Q. Right. So --

14:25:39 23 A. There's --

14:25:40 24 Q. -- in other words --

14:25:40 25 A. There's some analysis going on.

14:25:41 1 Q. There could be an MDR report to the FDA that
14:25:44 2 says, look, we've gotten some allegations of patient
14:25:47 3 industry -- patient and injury, we don't think they're
14:25:52 4 very credible for XYZ reasons, it doesn't look like
14:25:56 5 any credible person would find that there's a
14:25:57 6 reasonable risk here. Without reasonable evidence of
14:26:04 7 an association of the risk, there's no need for a
14:26:04 8 warning. Do you agree with that?

14:26:05 9 MS. EATON: Object to the form of the
14:26:06 10 question.

14:26:06 11 A. That may be one of the -- one of the
14:26:07 12 situations. And, you know, a warning is a -- has a
14:26:10 13 particular significance; otherwise, it would be
14:26:12 14 embedded in adverse effects.

14:26:13 15 Q. On the contrary, there is the other
14:26:16 16 situation where a manufacturer has no MDR reports
14:26:21 17 whatsoever but a warning could still be appropriate;
14:26:25 18 correct?

14:26:26 19 A. Give me that again, please.

14:26:27 20 Q. Sure. There could be a situation where a
14:26:29 21 manufacturer doesn't have any MDR reports, maybe it
14:26:34 22 hasn't even ever sold the product before, but a
14:26:37 23 warning could still be appropriate.

14:26:38 24 A. It would have to be a -- a generic type of
14:26:47 25 issue I suppose. Just speculating.

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14:26:50 1 Q. Well I mean, for instance, if a manufacturer
14:26:52 2 is going to make a product, put it out there on the
14:26:55 3 market, first time ever, nev -- product's never
14:26:57 4 existed before, right, and obviously in this case it
14:27:01 5 would have to be something substantially equivalent to
14:27:05 6 a prior product if we're talking about a 510(k)
14:27:07 7 product, but assume for me a moment we're talking
14:27:09 8 about a brand-new product. Okay?

14:27:12 9 A. Yes.

14:27:12 10 Q. There are manufacturers who have put man --
14:27:13 11 put warn -- put warnings on products that have never
14:27:17 12 been on the market before; correct?

14:27:18 13 A. Yes. Based upon literature, clinical
14:27:21 14 studies, very similar prior devices, whatever the case
14:27:24 15 may be.

14:27:26 16 Q. Sure. And -- and there may be no MDR
14:27:27 17 reports for that device.

14:27:28 18 A. Not yet, because it's not marketed.

14:27:30 19 Q. Right. And hopefully if it's warned right,
14:27:33 20 if the warnings are good, hopefully there will never
14:27:36 21 be any MDR reports for it; right?

14:27:39 22 A. Well unlikely, but yes.

14:27:40 23 Q. Well I mean there are -- there are some
14:27:41 24 devices out there, would you agree with me, that just
14:27:44 25 don't ever cause an adverse injury.

14:27:47 1 A. For the lower-risk devices, yes. For
14:27:48 2 anything other than that, that's unlikely.

14:27:51 3 Q. Right. So anything, par -- particularly
14:27:53 4 something that's an electrical device, something like
14:27:55 5 that --

14:27:55 6 A. A Class II device, it's unlikely there will
14:27:59 7 be no MDR reports.

14:27:59 8 Q. Okay. What I'm saying, though, is -- is if
14:28:02 9 a -- if a manufacturer has some sort of reasonable
14:28:04 10 evidence, letter, from the clinical literature, from
14:28:07 11 its own investigations, something like that, there are
14:28:08 12 situations where it would be appropriate to put a
14:28:10 13 warning on a device when there are no MDR reports.

14:28:15 14 A. I'd have to look at -- I'd have to look at
14:28:18 15 the specific instance. Hypothetically that may be the
14:28:21 16 case, but it's subject to the specifics --

14:28:25 17 Q. Sure.

14:28:25 18 A. -- of the case.

14:28:26 19 Q. But for instance, let's just brainstorm a
14:28:28 20 couple hypotheticals right now. If a company was in
14:28:32 21 possession of not just one, two, three, but numerous
14:28:34 22 clinical studies that suggested a reasonable
14:28:37 23 association of a risk with use of a product, that's
14:28:39 24 the kind of information that could justify a warning
14:28:43 25 even in the absence of any MDR reports.

14:28:44 1 A. Well it's all within the --

14:28:47 2 Perhaps, perhaps not, because it's all
14:28:49 3 within the context of the company's risk analysis,
14:28:54 4 risk management analysis whether or not there's a
14:28:58 5 credible association of the device to -- to the event.
14:29:06 6 So if the company has conducted analysis or has
14:29:10 7 otherwise assessed that and they've decided, no, it
14:29:14 8 really doesn't apply at this point in time, you know,
14:29:16 9 we don't have enough data, you know, they may decide
14:29:19 10 it's not yet time for a warning.

14:29:20 11 Q. Okay. And that kind of analysis that you're
14:29:23 12 talking about, that has to be done irrespective of if
14:29:26 13 there are MDR reports or not.

14:29:28 14 A. Well the whole -- the --

14:29:30 15 Right. Well, a device that's not yet
14:29:33 16 marketed, there is no experience, there are no MDR
14:29:35 17 reports, so the labeling is based upon those factors I
14:29:38 18 mentioned before: prior similar devices, literature
14:29:43 19 related to the device, the risk management analysis
14:29:47 20 which may lead to labeling of the device. So it's a
14:29:51 21 number of things.

14:29:51 22 Q. Okay. I want to go to your second reason
14:29:54 23 why a warning was not necessarily appropriate in this
14:29:57 24 case, okay, and that reason is the lack of a direct
14:30:01 25 causal relationship of infections to forced-air

14:30:04 1 warming. Do you remember that opinion?

14:30:05 2 A. Yes. I have it here.

14:30:06 3 Q. Yeah. And that's right there in front of
14:30:08 4 you as well.

14:30:09 5 In other words, nobody's proved a causal
14:30:12 6 relationship between infection and forced-air warming.

14:30:15 7 A. To my knowledge, I -- I haven't seen it. I
14:30:18 8 don't think any of your experts are attesting to that.

14:30:21 9 Q. Right. And so for that reason, because that
14:30:25 10 causal relationship has not been proved, warnings are
14:30:29 11 not necessarily appropriate.

14:30:30 12 A. Well then that -- that would lend itself to
14:30:34 13 not having it as a warning. There's other ways of
14:30:37 14 providing communication, but not necessarily a
14:30:39 15 warning.

14:30:40 16 Q. I mean a company is not going to give a
14:30:43 17 warning for a condition that hasn't been proved.

14:30:45 18 MS. EATON: Object to the form of the
14:30:46 19 question.

14:30:46 20 Q. A causal --

14:30:47 21 Excuse me. Let me rephrase that. A company
14:30:50 22 is not going to give a warning regarding a causal
14:30:51 23 relationship between a condition and a product that
14:30:53 24 hasn't been proved.

14:30:54 25 A. Well a warning --

14:30:54 1 MS. EATON: Object to the form of the
14:30:55 2 question.

14:30:56 3 A. Excuse -- yeah. A warning, there -- there
14:30:59 4 need not be a -- an established causal relationship,
14:31:04 5 but there must be strong evidence to -- to indicate a
14:31:07 6 warning as opposed to an adverse effect as opposed to
14:31:11 7 a precaution.

14:31:11 8 Q. Well your words in your report are there is
14:31:14 9 a lack of a direct causal relationship, that's why you
14:31:17 10 don't have to warn; right?

14:31:18 11 MS. EATON: Object to the form of the
14:31:19 12 question.

14:31:20 13 A. There's not strong --

14:31:20 14 MR. BANKSTON: Let's go ahead and get that
14:31:21 15 one. What's that about?

14:31:22 16 MS. EATON: You're taking one line out of
14:31:25 17 the context of an entire paragraph.

14:31:26 18 MR. BANKSTON: Oh. Is that an objection?

14:31:27 19 MS. EATON: Yes.

14:31:28 20 MR. BANKSTON: What is the objection?

14:31:29 21 MS. EATON: It's an objection to the form.
14:31:31 22 It mischaracterizes his report.

14:31:32 23 MR. BANKSTON: Okay. There's the objection.

14:31:33 24 MS. EATON: Yes.

14:31:34 25 MR. BANKSTON: All right.

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14:31:35 1 Q. So you see the sentence there, right, lack
14:31:43 2 of causal relationship?

14:31:43 3 A. Right.

14:31:44 4 Q. Okay. So let's look at that sentence
14:31:46 5 together.

14:31:59 6 Help out here, Mr. Ulatowski. What page are
14:32:01 7 you on?

14:32:01 8 A. Seventy-three.

14:32:02 9 Q. Okay.

14:32:03 10 A. Seventy-four.

14:32:06 11 Q. All right. So the paragraph, the thing that
14:32:08 12 I was taking out of context was --

14:32:10 13 There's four reasons in that paragraph;
14:32:14 14 right?

14:32:14 15 A. Right.

14:32:14 16 Q. And we're going through each one of them;
14:32:14 17 aren't we?

14:32:15 18 A. And in sum, the reasons are I would not have
14:32:18 19 a warning at this point in time.

14:32:19 20 Q. Okay. So the first one we talked about was
14:32:22 21 a paucity of MDR reports.

14:32:24 22 A. Right.

14:32:24 23 Q. Okay. So the second one is what you say is
14:32:27 24 the lack of a direct causal relationship of infections
14:32:29 25 to forced-air warming that Dr. David acknowledges in

14:32:32 1 his report.

14:32:33 2 A. Correct.

14:32:33 3 Q. Okay. So if there is a lack of a direct
14:32:36 4 causal relationship, that is something that the
14:32:39 5 company should take into mind and say this is a
14:32:42 6 justification for why not to warn.

14:32:44 7 A. It's one element to consider, and that's why
14:32:48 8 I list four elements. Taken together, I don't think a
9 warning is appropriate.

14:32:51 10 Q. Well you understand Dr. David in his report
14:32:54 11 cites the same Blue Book documents you do; right?

14:32:58 12 A. Yes, he does.

14:32:58 13 Q. Okay. And I noticed when I was looking at
14:33:01 14 Dr. David's -- when I was looking at Dr. David's
14:33:14 15 report at page 41 --

14:33:15 16 MR. BANKSTON: You got a copy?

14:33:16 17 MS. EATON: I do.

14:33:18 18 A. Is this for me to look at?

14:33:19 19 Q. No. I'm going to hand you one right here --

14:33:22 20 A. Oh.

14:33:24 21 Q. -- where I've got it open.

14:33:24 22 A. Okay.

14:33:24 23 Q. Do you see there towards the bottom of the
14:33:26 24 paragraph where it says "FDA Blue Book Guidance
14:33:29 25 Document?"

14:33:29 1 A. Hang on a second.

14:33:37 2 Yes, --

14:33:38 3 Q. Okay.

14:33:38 4 A. -- as I've explained to you.

14:33:39 5 Q. Yes. So in --

14:33:41 6 Dr. David, he cited on page 41 of his report

14:33:43 7 the exact same Blue Books document that you cited.

14:33:46 8 A. Right.

14:33:47 9 Q. Okay. And he includes the line that you
14:33:50 10 omitted, which is a causal relationship need not have
14:33:53 11 been proved.

14:33:53 12 A. I just explained that to you.

14:33:55 13 Q. I'm asking you what's in your report, sir.
14:33:57 14 That's not in your report; is it?

14:34:00 15 A. That statement is not in my report.

14:34:01 16 Q. Right. That statement was omitted.

14:34:04 17 And these are Blue Book documents that you
14:34:07 18 relied on and administered for years; correct?

14:34:10 19 A. Well I don't have a long answer here.

14:34:16 20 This -- this -- although there's some utility --

14:34:20 21 First of all, this is a guidance document,
14:34:22 22 it's not regulation; therefore, it -- it can be
14:34:25 23 applied to the degree the FDA chooses to apply it and
14:34:29 24 industry chooses to apply it, because there -- it's
14:34:33 25 not force of regulation. And secondly, if you read

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14:34:35 1 the guidance, it's based on FDA drug regulations, it's
14:34:41 2 not -- it's not a device regulations-based guidance.
14:34:45 3 It was created just as a -- at that point in time it
14:34:48 4 was intended as a stopgap until device regulations
14:34:51 5 were -- were improved and expanded. But -- but here
14:34:56 6 it is and -- but it's a --

14:34:58 7 If you read the foundation for this
14:35:01 8 guidance, it's a drug regulation-based guidance.
14:35:03 9 So --

14:35:04 10 Q. May not be so appropriate for this
14:35:07 11 situation.

14:35:07 12 A. May not be so appropriate, right.

14:35:11 13 Q. But you cited it in your report --

14 14 A. I did.

15 15 Q. -- in support for this opinion; --

16 16 A. I did.

17 17 Q. -- didn't you?

18 18 A. I mean it is what it is.

19 19 Q. The same document?

20 20 THE REPORTER: One at a time.

14:35:14 21 Q. You cited this in your opinion, the exact
14:35:15 22 document that Dr. David cited; right?

14:35:17 23 A. I did.

14:35:19 24 Q. Okay. And you reviewed Dr. David's report.

14:35:20 25 A. Yes, I did.

14:35:21 1 Q. In fact, your testimony is meant to address
14:35:23 2 his report.

14:35:24 3 A. Yes.

14:35:24 4 Q. And in fact, it's meant to address his
14:35:27 5 testimony with regard to whether there be should have
14:35:30 6 been a warning.

14:35:30 7 A. Yes.

14:35:30 8 Q. And you --

14:35:30 9 He gave the opinion there should have been a
14:35:32 10 warning; correct?

14:35:33 11 A. Yes. Which really wasn't a warning, but
14:35:36 12 yes.

14:35:36 13 Q. Okay. Well let's -- let's just say in any
14:35:39 14 way he doesn't think that there was an adequate
14:35:42 15 communication of the risks of this device.

14:35:45 16 A. Generally spoken, yes.

14:35:45 17 Q. Right. And he included documents like the
14:35:49 18 Blue Book guidance document in supporting his
14:35:52 19 opinions; right?

14:35:55 20 A. As I did, yes.

14:35:56 21 Q. And you gave the opinion that one of the
14:35:59 22 reasons the warning was not appropriate is because 3M
14:36:02 23 lacked proof of a direct causal relationship.

14:36:04 24 A. Yes, that's one of the elements of my
14:36:06 25 four- -- four-point rationale.

14:36:10 1 Q. But a causal relationship need not have been
14:36:12 2 proved to give a warning; correct?

14:36:14 3 A. Which I told you before you told me.

14:36:16 4 Q. Right.

14:36:18 5 Your report, then, which is meant to address
14:36:20 6 Dr. David on the contention that as long as there's
14:36:24 7 reasonable evidence, not a direct causal link, a
14:36:27 8 warning is appropriate, your rebuttal to that is one
14:36:31 9 of the reasons you don't give a warning is because
14:36:32 10 there's no direct causal relationship.

14:36:35 11 A. Yeah. I think that's part of this
14:36:36 12 litigation, to establish the reasonableness of that
14:36:40 13 association. So --

14:36:41 14 Q. And you don't --

14:36:43 15 A. Which I -- which I -- excuse me -- which I
14:36:46 16 think is, you know, open to great debate at this point
14:36:48 17 in time.

14:36:48 18 Q. And you don't see a glaring contradiction
14:36:52 19 between your opinion that that is a basis of not
14:36:52 20 warning and the Blue Book's guidance documents.

14:36:55 21 A. No, I --

14:36:56 22 In sum, no, because I found my opinion on
14:36:59 23 four points, and this is -- this is one element of
14:37:02 24 that.

14:37:02 25 Q. All right. Let's look at the third one.

14:37:04 1 The third one is the analysis of surgical-site
14:37:06 2 infections in the 3M risk management report; correct?
14:37:09 3 A. Yes.
14:37:10 4 Q. All right. So the defendant --
14:37:12 5 MR. BANKSTON: Let's take a look at that
14:37:13 6 real quick. Let's talk about this --
14:37:23 7 Let's have that marked.
14:37:33 8 (Ulatowski Exhibit 7 was marked for
9 identification.)
14:37:39 10 THE WITNESS: Boy, this is an eye test. You
14:37:41 11 know, I can blow mine up on the screen, but --
12 BY MR. BANKSTON:
14:37:44 13 Q. Well good thing I'm not going to be asking
14:37:47 14 you a bunch of words in it, but I do want to bring to
14:37:49 15 your attention that is the document that you cited as
14:37:51 16 the 3M risk management report; right?
14:37:53 17 A. Yeah. Although I'm having trouble reading
14:37:55 18 it. But go ahead.
14:37:56 19 Q. Well we can just compare the Bates number to
14:37:59 20 what you cited in your report; right?
14:38:01 21 A. No, I'm not denying that, I'm just saying I
14:38:03 22 can't --
14:38:03 23 Q. Yeah. And again, I don't --
24 A. My glasses --
14:38:06 25 Q. I'm not concerned about the content at this

14:38:06 1 point. I don't really care what it says. I'm trying
14:38:09 2 to say that this is the document, the 3M risk
14:38:11 3 management report, that's cited in your report.

14:38:14 4 A. Okay.

14:38:15 5 Q. Correct?

14:38:15 6 A. I believe so.

14:38:17 7 Q. Okay.

14:38:18 8 A. I recognize it --

14:38:19 9 Q. Okay.

14:38:19 10 A. -- generally.

14:38:20 11 Q. So this chart in front of you, this -- that
14:38:24 12 they've made -- let me try to get this on --

14:38:27 13 Let me make sure I understand. So defendant
14:38:31 14 made a chart saying that their billion-dollar
14:38:32 15 investment was not to blame and you find that
14:38:35 16 compelling.

14:38:36 17 A. It's --

14:38:37 18 MS. EATON: Object to the form of that
14:38:39 19 question.

14:38:40 20 A. I find FMBAs to be important documents to
14:38:44 21 assess.

14:38:44 22 Q. And you've just reviewed this chart; right?

14:38:48 23 A. Well there --

14:38:49 24 It's part of a larger document, but yes --

25 Q. Have you reviewed --

14:38:51 1 A. -- it's a part of it.

14:38:52 2 Q. Did you review that larger document?

14:38:54 3 A. Yes.

14:38:54 4 Q. Okay. And what methodologies were
14:38:56 5 undertaken to determine this risk?

14:38:58 6 A. By 3M?

14:39:00 7 Q. Uh-huh.

14:39:01 8 A. There's a risk management standard that 3M
14:39:05 9 and -- and almost the entire medical device industry
14:39:08 10 applies in regards to identifying and managing risks,
14:39:14 11 dealing with risks.

14:39:14 12 Q. Okay.

14:39:15 13 A. So I --

14:39:15 14 Which surprised me Dr. David doesn't even
14:39:18 15 reference, but ISO 14971. So this is very much in
14:39:24 16 line with -- with that manner.

14:39:26 17 Q. Okay. So this chart here and these
14:39:29 18 conclusions that 3M reached, because you look at that,
14:39:34 19 you think there shouldn't have been a warning made;
14:39:36 20 correct?

14:39:36 21 A. Yes. And this is -- this is retrospective
14:39:40 22 as I viewed it and -- and as discussed in this, so
14:39:45 23 it's not only going forward, I -- in my opinion it's
14:39:48 24 a -- it's a backward-looking document as well.

14:39:52 25 Q. Okay. And what are you meaning exactly by

14:39:54 1 that?

14:39:54 2 A. Well 3M's taking a look on this particular
14:39:58 3 date and making its decisions, but of course we know
14:40:01 4 time is -- this -- this issue has not reared its head,
14:40:08 5 airborne contamination, whenever this document was --
14:40:12 6 was decided upon. I can't -- I can't read the date on
14:40:15 7 this particular page.

14:40:16 8 Q. I don't think there's a date on it which is
14:40:18 9 what I was going to ask you. When did this happen?

14:40:21 10 A. Yeah. There -- there --

14:40:22 11 This is part of a larger document where
14:40:23 12 there is -- there are dates.

14:40:24 13 Q. Okay. Do you know when this happened?

14:40:27 14 A. This was --

14:40:30 15 This is relatively recent I think.

14:40:32 16 Q. Not when the decisions were being made
14:40:34 17 whether to put a warning on this device; correct?

14:40:36 18 A. And that's why I say its -- it's, in my
14:40:40 19 opinion, based upon the foundation here, useful in
14:40:45 20 retrospect as well, because there's no less
14:40:47 21 information now than there was years ago, there's more
14:40:52 22 information now. So if -- if -- you would expect new
14:40:55 23 information to be amassed that would, if I were to go
14:41:00 24 on plaintiffs' side, say, well, the risk is greater,
14:41:03 25 the risk is more prominent, there's more evidence.

14:41:06 1 What I'm saying is roll this back to 1997, whatever,
14:41:11 2 and what was known then. Well even less, and the
14:41:15 3 risk, if there is one, was even less apparent. So --

14:41:18 4 Q. Well what about the studies that 3M is using
14:41:21 5 to say there's no risk, things like Dr. Sessler and
14:41:23 6 Dr. Olmstead's study? That did not exist back then,
14:41:26 7 did it, back at the time of clearance and decisions
14:41:29 8 made on warnings?

14:41:30 9 A. No. I think that's my point, that data and
14:41:32 10 information has -- has evolved over time but it hasn't
14:41:36 11 changed the profile over time. There's pros and cons,
14:41:42 12 there's more or less, there's this and that, but I
14:41:45 13 don't think the needle moved any in regard to the
14:41:46 14 outcome.

14:41:47 15 Q. Really. Okay.

14:41:48 16 A. You know, 3M has their position, their
14:41:53 17 foundation, their conclusions, and of course
14:41:54 18 plaintiffs have their conclusions as well.

14:41:56 19 Q. And a lot of independent people have their
14:41:59 20 conclusions, too; right?

14:42:00 21 A. Right, that it's not a problem.

14:42:03 22 Q. And that it is a problem.

14:42:03 23 A. Well there you, pros and cons.

14:42:05 24 Q. Yeah. You've got a lot of different people
14:42:08 25 concluding a lot of different things; right? Correct?

14:42:13 1 A. You've got different people concluding
14:42:13 2 different things, strengths and weakness of all the
14:42:15 3 data.

14:42:16 4 Q. Uh-huh.

14:42:17 5 A. And so that -- that all needs to be taken
14:42:20 6 into account.

14:42:21 7 Q. And --

14:42:23 8 A. I think -- I think 3M's position in this
14:42:24 9 assessment is -- is sufficiently well founded at this
14:42:27 10 point in time.

14:42:28 11 MS. EATON: And I would just pause and ask
14:42:30 12 you to remember to wait for a question.

14:42:33 13 THE WITNESS: Okay.

14:42:35 14 MS. EATON: Thank you.

14:42:35 15 Q. When it comes to people's independent
14:42:37 16 opinions, people who have no dog in this fight, none
14:42:41 17 of those are cited in your four reasons for not to
14:42:44 18 warn; right? The only one -- like the only person
14:42:47 19 source of information that you've cited is the most
14:42:50 20 biased person in the equation; correct?

14:42:52 21 MS. EATON: Object to the form of the
14:42:54 22 question.

14:42:57 23 A. Well for whatever reason, you know, I
14:43:00 24 certainly do address those, you know, ECRI and the
14:43:05 25 Periprosthetic Consensus opinion, I do discuss those

14:43:09 1 later, so I haven't -- I don't neglect them. And

14:43:12 2 they're supportive of 3M's position. But --

14:43:14 3 So my point here is -- is that a risk

14:43:21 4 management process, of which this is a part, is one of

14:43:24 5 the vehicles whereby labeling instructions are either

14:43:30 6 found to be necessary or unnecessary.

14:43:34 7 Q. Let's talk a little bit about those

14:43:35 8 independent organizations you just brought up. Let's

14:43:37 9 first talk about the International Consensus on

14:43:39 10 Periprosthetic Joint Infection. That's something you

14:43:42 11 rely on?

14:43:42 12 A. That's something I comment on in the report.

14:43:44 13 Q. Do you understand that 87 percent of the

14:43:47 14 delegates agreed in that consensus statement that they

14:43:51 15 recognized the theoretical risk of forced-air warming?

14:43:53 16 A. Their conclusions are stated in their

14:43:58 17 conclusions, so --

14:43:58 18 Q. That's reasonable evidence of an association

14:44:01 19 of a potential risk of this product; isn't it?

14:44:03 20 MS. EATON: Object to the form --

14:44:04 21 Well, I withdraw my objection.

14:44:06 22 A. No, I -- I think this is -- it's supportive

14:44:08 23 of 3M's position that -- that it's not evident to

14:44:13 24 the -- to the degree that Dr. Augustine would have

14:44:16 25 people think.

14:44:16 1 Q. All right. All the consensus statement
14:44:19 2 says, the entirety of it is we recognize the
14:44:22 3 theoretical risk of forced-air warming and the fact
14:44:24 4 that no study has ever conclusively proved the
14:44:27 5 existence of an infection. You understand that those
14:44:30 6 are the two conclusions.

14:44:30 7 A. And there should be no change in therapy and
14:44:33 8 use of the product.

14:44:33 9 Q. Right, exactly. They conclude that there's
14:44:35 10 no change in use of the product.

14:44:37 11 A. Right.

14:44:38 12 Q. You're not pulling it out of hospitals.

14:44:40 13 A. Don't pull it out, keep using it.

14:44:42 14 Q. Yeah, exactly.

14:44:42 15 A. Right.

14:44:42 16 Q. You don't agree with me, though, that when
14:44:45 17 87 percent of those delegates agree and recognize the
14:44:49 18 theoretical risk, that that isn't some evidence of a
14:44:50 19 reasonable association between the products and that
14:44:54 20 risk?

14:44:54 21 A. You have to rely upon the official position
14:44:58 22 as stated by the group, which is their -- the
14:44:59 23 statement they made.

14:45:00 24 Q. Which has nothing to do about whether the
14:45:02 25 product should have warnings or not; right? That's

14:45:04 1 not what they're there to decide.

14:45:07 2 A. Well then why are you asking me why didn't I
14:45:09 3 cite it?

14:45:09 4 Q. I'm just trying to figure out where -- if
14:45:10 5 there exists in these independent groups reasonable
14:45:14 6 evidence of the association between a risk of a
14:45:16 7 product, and you would agree with me the International
14:45:16 8 Concensus is one such -- is one such document.

14:45:20 9 A. Their statement stands on its own, and their
14:45:22 10 statement that the device can continue to be used with
14:45:25 11 no modification.

14:45:26 12 Q. Let's talk about ECRI. You know that when
14:45:29 13 ECRI did a literature review, it said not a single
14:45:32 14 study met their inclusion criteria, not a single one.
14:45:36 15 Do you recognize that?

14:45:36 16 MS. EATON: If you're going to ask him
14:45:39 17 questions about the ECRI report, I would ask that you
14:45:39 18 put it front of him so he can be precise.

14:45:40 19 MR. BANKSTON: I don't have it. He brought
14:45:42 20 it up. I did never think I was going to be talking
14:45:45 21 about it. He brought it up, so I'm asking questions
14:45:46 22 about it.

14:45:47 23 MS. EATON: That's fine.

14:45:49 24 A. What's your question again?

14:45:49 25 Q. They -- they -- of all --

14:45:49 1 When they did a literature review and they
14:45:50 2 reviewed all the literature on it, they didn't find a
14:45:53 3 single study that met their inclusion criteria.

14:45:55 4 A. Well yes, they did --

14:45:57 5 As -- as any literature search will do,
14:46:02 6 you'll begin with everything and narrow it down to
14:46:05 7 particular criteria that you've established. That's
14:46:07 8 always the case with a very rigorous data analysis.
14:46:10 9 I've done that many times.

14:46:11 10 Q. It's always the case that you don't find a
14:46:13 11 single study that meets the inclusion criteria?

14:46:16 12 A. Well I think they did arrive at -- at -- at
14:46:20 13 a few studies that -- that were important to them, and
14:46:23 14 they commented on that in their report.

14:46:25 15 Q. Yeah. They said there was a couple studies
14:46:27 16 that came close. Do you remember that?

14:46:28 17 A. Fine. But that doesn't say much about the
14:46:30 18 plaintiffs' studies either I suppose; right?

14:46:31 19 Q. It doesn't really say anything much about
14:46:34 20 anything; does it?

14:46:34 21 A. Well then why are we here?

14:46:34 22 MS. EATON: Object to the form of the
14:46:35 23 question.

14:46:36 24 Q. What's that, sir?

14:46:36 25 A. Then why are we here?

1 Q. Well you cited it as a re -- support for
14:46:43 2 your idea that there has been a finding that a warning
14:46:48 3 isn't appropriate, that there's no reasonable evidence
14:46:48 4 of an association between a risk, and what I want to
14:46:51 5 understand from you, sir, is what you think in ECRI's
14:46:55 6 position supports that statement.

14:46:58 7 A. Well first of all, we've gotten off track
14:47:00 8 here. We started at here are my four positions to
14:47:04 9 substantiate, and you asked why didn't you reference
14:47:08 10 anything else. Well I said why I talk about other
14:47:11 11 things, but not in this instance. So -- so why don't
14:47:15 12 we just concentrate on what I said to support the --
14:47:19 13 as a foundation for my statement.

14:47:21 14 Q. Sir, you're the one who volunteered to me
14:47:23 15 that you were relying on independent organizations
14:47:25 16 such as ECRI and the International Consensus; correct?

14:47:29 17 A. No. I -- I think the discussion began, you
14:47:30 18 know, why didn't you talk about ECRI and that.

14:47:33 19 Q. Okay. So let's get to --

14:47:33 20 A. And I said why I didn't.

14:47:35 21 Q. So then let's go back to your warning
14:47:36 22 opinions, which is: When you cite your four reasons
14:47:39 23 for your warnings, you don't cite anybody who is
14:47:43 24 independent. You have no independent support for that
14:47:46 25 opinion.

14:47:46 1 A. No. It's unnecessary at this point in time
14:47:48 2 because I provide foundation for my opinion.

14:47:51 3 Q. Instead, we're just going to rely on the
14:47:54 4 information by the people who have an enormous amount
14:47:56 5 to lose.

14:47:58 6 MS. EATON: Object to the form of the
14:47:58 7 question.

14:47:59 8 A. No, sir. I -- I rely upon the typical
14:48:03 9 foundation for labeling statements, such as warnings
14:48:08 10 in labeling, which this is one of those primary
14:48:12 11 sources right here.

14:48:12 12 Q. Another thing about ECRI, they also found
14:48:15 13 that these concerns of risk are particularly
14:48:18 14 worrisome. Do you remember them saying that?

14:48:20 15 MS. EATON: Object to the form of the
14:48:21 16 question.

14:48:21 17 A. Well I have their statement in my report.

14:48:24 18 Q. Sure.

14:48:24 19 A. I'd have to read it.

14:48:25 20 Q. All right. And so these ones --

14:48:27 21 The International Consensus statement and
14:48:29 22 the ECRI statement, these are the two of the
14:48:30 23 independent things that you think are good for the
14:48:33 24 defendants' side; right?

14:48:34 25 MS. EATON: Object to the form of the

14:48:37 1 question.

14:48:37 2 A. You know, we can read their -- their
14:48:40 3 findings again. It's remarkable that and supportive
14:48:43 4 that the perioperative group said keep using the
14:48:46 5 device.

14:48:48 6 Q. There are other independent groups and other
14:48:50 7 independent authors and other literature reviews which
14:48:53 8 have been far less favorable on the subject and
14:48:56 9 recommended alternative warning therapies; correct?

14:48:58 10 MS. EATON: Object to the form of the
14:49:01 11 question.

14:49:01 12 A. Well I guess that's all going to come out.
14:49:02 13 I haven't commented on that.

14:49:04 14 Q. Okay.

14:49:04 15 A. But ECRI and -- you know, I point to them in
14:49:07 16 my report, not in this section. They're an informed
14:49:12 17 group, they provide input to -- on public health
14:49:16 18 matters to -- to the United States. I've had
14:49:19 19 interactions with them before on many topics and find
14:49:22 20 them to be credible and useful.

14:49:24 21 Q. And that is an organization that has
14:49:27 22 recommended that further study be performed on this
14:49:30 23 product.

14:49:30 24 A. Fine.

14:49:31 25 MS. EATON: Could we take a break?

14:49:32 1 Q. Is that correct?

14:49:33 2 A. I'd have to read their report again.

14:49:40 3 Q. Okay.

14:49:40 4 MS. EATON: I'd like to take a break.

14:49:43 5 MR. BANKSTON: Okay.

14:49:43 6 THE REPORTER: Off the record, please.

14:58:15 7 (Recess taken.)

14:58:15 8 BY MR. BANKSTON:

14:58:20 9 Q. Mr. Ulatowski, portions of your report
14:58:24 10 discuss scientific literature; correct?

14:58:26 11 A. I refer to it.

14:58:27 12 Q. Correct. Things you have reviewed include
14:58:32 13 the scientific literature cited in Dr. David's report.

14:58:36 14 A. Right. Early on, as I mentioned I think
14:58:38 15 earlier in the day, I -- I received virtually every
14:58:45 16 relevant report related to the Bair Hugger or the
14:58:48 17 technology, both pro and con.

14:58:52 18 Q. You realize a large amount of the authors
14:58:57 19 who have written and studied the Bair Hugger have been
14:59:01 20 deposited in this case.

14:59:01 21 A. Well I guess I may not know everyone who's
14:59:04 22 been deposited or have -- have read every one, but, you
14:59:09 23 know, I imagine there's been quite a number of them.

14:59:12 24 Q. I notice there's not a deposition transcript
14:59:15 25 on your reviewed list of Dr. Belani, for instance. Do

14:59:20 1 you know who Dr. Belani is?

14:59:21 2 A. Doesn't ring a bell.

14:59:22 3 Q. Okay. He's one of the authors in Dr.

14:59:25 4 David's report who had given one of the --

14:59:28 5 Are you aware he's been deposed?

14:59:30 6 A. You know, if Dr. David referred to it in his

14:59:33 7 report, I did ask for all the references Dr. David had

14:59:40 8 so I could understand whether or not I had seen those.

14:59:44 9 So, you know, if -- if it was in one of the records

14:59:51 10 provided to me as I requested, you know, I may have

14:59:54 11 seen it, but I -- I don't recall it offhand. There's

14:59:57 12 so many of them.

14:59:58 13 Q. Your understanding is you -- you have been

15:00:00 14 provided or it was your intent to be provided with

15:00:02 15 everything cited in Dr. David's report?

15:00:04 16 A. Yes.

15:00:04 17 Q. Okay. But in terms of these physicians and

15:00:11 18 researchers, Dr. Nachtsheim, Dr. Legg, Dr. Hammer, Dr.

15:00:17 19 Reed, Dr. McGovern, Dr. Gauthier, Dr. Leaper, Dr.

15:00:23 20 Litchy, Mr. Albrecht, none of those depositions are

15:00:25 21 things that you read in coming to your conclusions

15:00:28 22 about the scientific evidence in this case?

15:00:30 23 A. Well again, as -- as we discussed earlier,

15:00:36 24 I -- I don't make a -- an affirmative statement about,

15:00:41 25 you know, the benefits or -- or data related to the

15:00:47 1 studies, --

15:00:48 2 Q. Okay.

15:00:49 3 A. -- and -- and that's simply the case. I
15:00:52 4 just, for example, comment on Dr. David's approach to
15:00:58 5 analyzing the literature indicating that he appeared
15:01:01 6 to be very selective in what he looked at.

15:01:04 7 Q. All right. You have -- you have no training
15:01:07 8 as an orthopedic physician; correct?

15:01:08 9 A. No.

15:01:09 10 Q. Okay. You have no training or --
15:01:13 11 Not an infectious disease doctor; right?

15:01:15 12 A. I'm not an infectious disease doctor.

15:01:18 13 Q. All right. One of --

15:01:19 14 You've got an opinion in your case
15:01:20 15 addressing Dr. William Jarvis, right, and his
15:01:23 16 opinions?

15:01:24 17 A. Related to HICPAC.

15:01:27 18 Q. Right. Do you feel qualified to address Dr.
15:01:32 19 Jarvis's opinions as -- his clinical conclusions as an
15:01:32 20 infectious disease doctor?

15:01:34 21 A. No.

15:01:34 22 Q. Okay. You're not an expert in filtration.

15:01:37 23 A. No, I wouldn't call myself an expert. I
15:01:40 24 used it in the course of my laboratory work. But no.

15:01:43 25 Q. You're not an expert in what we would call

15:01:46 1 HVAC. Are you familiar with that term?

15:01:48 2 A. Of what?

15:01:50 3 Q. HVAC.

15:01:53 4 A. HVAC?

15:01:53 5 Q. H-V-A-C.

15:01:54 6 A. No.

15:01:54 7 Q. Okay.

15:01:55 8 A. No, I'm not an expert in HVAC.

15:01:57 9 Q. You're not an expert in OR design.

15:02:00 10 A. No, I am not.

15:02:00 11 Q. You are not an expert in particulate flow in

15:02:04 12 the air.

15:02:05 13 A. No.

15:02:05 14 Q. Not an expert in physics.

15:02:07 15 A. No.

15:02:08 16 Q. Not an expert in computational fluid

15:02:10 17 dynamics.

15:02:11 18 A. No.

15:02:12 19 Q. Not an expert in epidemiology.

15:02:14 20 A. No.

15:02:15 21 Q. Okay. You won't be offering any testimony

15:02:21 22 in this case today or at trial on any of those issues

15:02:25 23 we just talked about right now.

15:02:26 24 A. No. I haven't in my report. If I'm asked,

15:02:30 25 you know, I guess I'll have to defer. But who knows?

15:02:34 1 Q. Okay. I want to jump back into your
15:02:40 2 discussion about warnings, and let's talk about the
15:02:44 3 fourth reason. So you might want to go --
15:02:46 4 (Discussion off the stenographic record.)
15:02:46 5 A. Can we go back to that -- refer me to that
15:02:49 6 page because I closed it.
15:02:50 7 Oh, yeah, 75 -- 73-75.
15:02:53 8 Q. I just wanted to make sure I heard you
15:02:55 9 correctly on the last answer because there was a word
15:02:59 10 that has a homophone to it, and it is when you say --
15:03:03 11 Did you say you'd defer to those experts or
15:03:07 12 you'd confer with those experts?
15:03:09 13 A. In my last --
15:03:10 14 Q. In your last answer about your statements
15 15 to -- about conclusions that experts might draw in
15:03:12 16 this case.
15:03:12 17 A. Our -- our --
15:03:12 18 I think our last example was the airflow,
15:03:15 19 air particulates or something. I say I'd defer to
15:03:19 20 experts on that.
15:03:19 21 Q. Okay. Defer.
22 A. Defer.
15:03:22 23 Q. Okay. I want to talk to you about --
15:03:25 24 Back on 73 you have your reasons that you
15:03:27 25 have given concerning why a warning wasn't

15:03:29 1 appropriate, and the last one that we hadn't gotten to
15:03:33 2 yet was the existing blanket and taping design and
15:03:37 3 blanket labeling and filter mitigation. Those -- I
15:03:41 4 want to break those down each as a piece. Okay?

15:03:44 5 With respect to the taping design, do you
15:03:50 6 have anything you can offer me today that you're
15:03:52 7 relying on that would support the idea that this
15:03:55 8 taping design mitigates the risk of airborne
15:03:58 9 contamination and infection in orthopedic surgeries?

15:04:01 10 A. That's what it's intended to do.

15:04:04 11 Q. Right. And I understand I could -- I could
15:04:06 12 make something -- I could -- I could make something in
15:04:09 13 my garage that's intended to do a lot of things, but I
15:04:11 14 may not be necessarily successful. Correct?

15:04:13 15 A. Well theoretically, yes. I mean a physical
15:04:19 16 barrier is -- we talk about filtration, but a physical
15:04:23 17 barrier is a physical barrier, so if there's an
15:04:26 18 effective taping mechanism, that should be an
15:04:28 19 effective physical barrier without efficiency issues
15:04:33 20 or about transmission issues. It should be all or
15:04:34 21 none.

15:04:34 22 Q. And what if anything are you relying on to
15:04:37 23 say that there is an effective taping barrier?

15:04:40 24 A. Well the -- the label --

15:04:44 25 The submissions for blankets, 510(k)

15:04:46 1 submissions, indicated that these blankets should be
15:04:49 2 taped to prevent -- to prevent airflow.

15:04:54 3 Q. That -- that was something submitted by Dr.
15:04:57 4 Augustine.

15:04:57 5 A. Right, early on. And there's many blanket
15:04:59 6 submissions stating that.

15:05:00 7 Q. Dr. Augustine's that guy you don't find
15:05:02 8 credible at all.

15:05:03 9 A. Well the 510(k)s are reviewed by FDA and
15:05:06 10 either found credible by FDA because of what's
15:05:09 11 submitted or because of what FDA knows.

15:05:12 12 Q. Okay.

15:05:12 13 A. I had on my staff seven OR nurses, so if
15:05:16 14 they saw things that were not ringing true, they could
15:05:22 15 pick it up.

15:05:22 16 Q. What would --

15:05:22 17 What did the FDA do in order to determine
15:05:24 18 that the taping mechanism was effective?

15:05:27 19 A. Well I don't think FDA did any testing or
15:05:32 20 any evaluation. It was based upon --

15:05:35 21 You know, the company would be expected to
15:05:37 22 evaluate the taping mechanism and effective --
15:05:41 23 effectiveness of that.

15:05:41 24 Q. What did the company do to evaluate the
15:05:43 25 taping mechanism and the effectiveness of that?

15:05:45 1 A. I don't recall the specific testing in
15:05:47 2 regard to the blankets. Those are pretty -- some of
15:05:51 3 them are pretty old 510(k)s.

15:05:51 4 Q. Okay. Is it your contention that the
15:05:53 5 company did something to test these blanket strips for
15:05:58 6 airborne contamination?

15:06:00 7 A. Individually, yes, or relying upon prior
15:06:03 8 experience of other designs and other taping
15:06:07 9 mechanisms. That would be my answer.

15:06:09 10 Q. Do you have any idea if there's ever been a
15:06:11 11 product like the Bair Hugger before that had a taping
15:06:13 12 mechanism?

15:06:15 13 A. It wouldn't necessarily be a blanket taping
15:06:17 14 mechanism, could be just a taping or -- of particular
15:06:20 15 drapes and gowns and things like that.

15:06:22 16 Q. Okay. But in terms of any actual evidence
15:06:27 17 that the Bair Hugger's taping mechanism does anything
15:06:30 18 at all, you don't have anything to offer me today.

15:06:34 19 A. Well I'd have to look back at the studies
15:06:36 20 that were conducted within the design history file.
15:06:40 21 I -- I think I'd probably find some evaluation of
15:06:43 22 airflow around the blankets.

15:06:47 23 Q. You would agree that that design history
15:06:47 24 file, that's something you've reviewed; right?

15:06:49 25 A. Yes.

15:06:49 1 Q. That's something you've reviewed
15:06:51 2 conscientiously. It's a pretty important document in
15:06:54 3 this case.

15:06:54 4 A. Yes. I looked through it.

15:06:55 5 Q. Okay. What if anything in the DHF concerns
15:07:00 6 airborne contamination?

15:07:05 7 A. Well I think inasmuch as the 510(k)s
15:07:21 8 themselves are by their nature inherently part of the
15:07:24 9 design history file, you know, there's discussion in
15:07:27 10 the 510(k)s early on of airborne contamination, and of
15:07:31 11 course the Hall and Zink article early on. All the
15:07:35 12 testing done by 3M or Arizant, whoever it may have
15:07:43 13 been at a certain point in time, all that testing and
15:07:46 14 evaluation should reside in the design history book.

15:07:49 15 Q. You reviewed it; right?

15:07:50 16 A. Yes. And I reviewed --

15:07:52 17 Q. Conscientiously.

15:07:53 18 A. Yes. And I looked at the other tests, not
15:07:56 19 with an expert eye but just to understand that there
15:08:00 20 was testing conducted. And what I'm saying is my view
15:08:03 21 of the design history file, what constitutes the
15:08:05 22 design history file is -- is all -- any testing
15:08:09 23 concerning the device, its design, its operation, that
15:08:12 24 should be embodied in the design history file.

15:08:14 25 Q. Should be. Is it?

15:08:15 1 A. Doesn't necessarily have to reside
15:08:18 2 physically in the design history file. It may be
15:08:20 3 referred to or -- or found through reference.

15:08:24 4 Q. Well what I'm trying to get at is you've
15:08:27 5 told me you're relying on the design history file for
15:08:29 6 your opinion that the taping design is effective, and
15:08:32 7 I want to know what's in the design history file that
15:08:34 8 would indicate that the taping is effective or
15:08:35 9 addresses airborne contamination in any way.

15:08:37 10 A. Well that's not entirely what I said. What
15:08:40 11 I said is I'd have to review the design history file
15:08:44 12 again and any testing that's included and the 510(k)s
15:08:47 13 to look for that, as well as I have said -- I think I
15:08:51 14 said I understand through my reading of test results
15:08:59 15 that there had been tests of airflow in and around the
15:09:04 16 blanket area, and so, you know, that -- that would
15:09:06 17 constitute relevant information.

15:09:09 18 But there's also a foundation of this is not
15:09:17 19 particularly -- I would expect not a particularly new
15:09:21 20 procedure for there to be taping of -- of gowns and
15:09:25 21 drapes in a certain fashion, so it -- it wouldn't
15:09:28 22 create -- it wouldn't be a -- a new phenomenon that
15:09:31 23 drapes and gowns and blankets would be taped.

15:09:34 24 Q. Okay. But a forced-air warming blanket
15:09:36 25 cover that expels air out of it into the area of the

15:09:40 1 surgical site, it's a lot different than a drape;

15:09:43 2 isn't it?

15:09:43 3 MS. EATON: Object to the form of the

15:09:44 4 question.

15:09:44 5 A. Well I don't think it's been determined that

15:09:47 6 it expels air into the surgical site, but --

15:09:51 7 Q. Certainly --

15:09:51 8 A. What's the other aspect of your question?

15:09:52 9 Q. Well certainly, first of all, the device has

15:09:54 10 a coverlet blanket with perforations in it that expel

15:09:58 11 air in and near the surgical site.

15:09:59 12 MS. EATON: Object to the form of the

15:10:02 13 question.

15:10:02 14 Q. And you don't dispute that; do you?

15:10:03 15 A. Well there are perforations that expel air,

15:10:05 16 but I guess isn't it the contention of the litigation

15:10:09 17 whether or not there is activity in the surgical-site

15:10:12 18 area?

15:10:12 19 Q. Can you describe to me anything else in that

15:10:16 20 operating room that is closer to the surgical site

15:10:18 21 than the Bair Hugger blanket?

15:10:20 22 A. Besides the participants in the --

15:10:22 23 Q. Besides the participants.

15:10:23 24 A. As well as any other devices that may be

15:10:26 25 used, anesthesia devices, any other devices used

15:10:29 1 during operation?

15:10:30 2 Q. Do you think anes --

15:10:31 3 A. There's multiple devices used during an
15:10:34 4 orthopedic operation.

15:10:34 5 Q. Do you think anesthesia devices are closer
15:10:37 6 to the surgical site than the Bair Hugger blanket?

15:10:39 7 A. May be. May be. Depends on how the anes --
15:10:41 8 particular anesthesiologist has positioned the
15:10:45 9 devices.

15:10:45 10 Q. Have you seen a Bair Hugger?

15:10:45 11 A. Yes.

15:10:45 12 Q. You held one in your hands?

15:10:47 13 A. No, I haven't held one in my hands.

15:10:49 14 Q. Never looked at it, seen how it works?

15:10:51 15 A. Not physically. I haven't -- haven't
15:10:54 16 received one or -- or used one.

15:10:56 17 Q. Never viewed one in operation?

15:10:58 18 A. No, I don't -- well other --

15:11:01 19 Yes. In regard to videos, yes.

15:11:03 20 Q. You've seen one being used in orthopedic
15:11:06 21 surgery?

15:11:09 22 A. I may have seen simulations, yes, for
15:11:14 23 example.

15:11:14 24 Q. Okay. Let's talk about the filter, because
15:11:26 25 one of your -- part of the fourth reason there is

15:11:27 1 filter mitigation; correct?

15:11:28 2 A. Yes.

15:11:29 3 Q. Okay. Do you have any specific information
15:11:30 4 to offer me that the filter is effective at preventing
15:11:34 5 airborne contamination?

15:11:34 6 A. Well that's a subject of this whole ball
15:11:38 7 game I suppose.

15:11:39 8 Q. That's why I'm asking if you got any
15:11:42 9 opinions on it.

15:11:42 10 A. Well, there's information both pro and con,
15:11:47 11 pro on the part of the company, con on the part of the
15:11:48 12 plaintiffs, each making their arguments based upon
15:11:54 13 literature, based upon their own testing and
15:11:56 14 evaluation, based upon that type of information. So,
15:12:01 15 you know, all I can say is there is -- there's a lot
15:12:07 16 of information that's, I understand, contentious and
15:12:11 17 everybody -- every camp has a position on it.

15:12:14 18 Q. Nonetheless, you say that the fact that the
15:12:16 19 filter acts as a mitigating element is a reason not to
15:12:19 20 warn; right?

15:12:20 21 A. Well I don't think it's --

15:12:21 22 It's indisputable that a filter arguably,
15:12:26 23 whatever -- to what degree, but a filter is -- is a
15:12:31 24 mitigation. I think -- I think people are arguing
15:12:34 25 shades of mitigation, effectiveness of mitigation, but

15:12:39 1 nonetheless it is a mitigation.

15:12:42 2 Q. You don't have any experience to sit here
15:12:42 3 today and tell me that that filter prevents the
15:12:45 4 passing through of nosocomial infection-type organisms
15:12:50 5 through it and towards the patient.

15:12:52 6 A. Well you've got a lot going on there in
15:12:54 7 that --

15:12:54 8 Q. Uh-huh.

15:12:54 9 A. -- in that point.

15:12:55 10 Q. Yup. Let's -- let's break it down a piece
15:12:58 11 at a time actually.

12 A. And that's a --

15:13:01 13 Q. Let's -- let's do it that way. I'll
15:13:01 14 withdraw that question.

15:13:01 15 Do you have any information about what the
15:13:03 16 typical size of a nosocomial infection -- infectious
15:13:07 17 element is?

15:13:07 18 A. Well you're drawing upon my microbiology
15:13:11 19 experience. I -- I have a degree in microbiology.
15:13:14 20 It -- it -- that --

15:13:16 21 That aspect has not been a particular focus
15:13:19 22 of my expertise at FDA, but it's -- it's certainly
15:13:22 23 larger than .2 micron, and some are -- are actually
15:13:25 24 quite large, in the .4, .5 and up.

15:13:29 25 Q. You would agree with me you're not qualified

15:13:31 1 to offer an opinion on the effectiveness of filtration
15:13:35 2 or the mechanics of filtration.

15:13:37 3 A. I think I already stated I'm not a
15:13:38 4 filtration expert.

15:13:39 5 Q. Correct. And so I just want to make sure
15:13:42 6 that in terms of the opinions you're giving today,
7 you're not going to be test -- talking about the
15:13:44 8 efficiency or effectiveness at preventing airborne
15:13:46 9 contamination of any given filter.

15:13:48 10 MS. EATON: Object to the form of the
15:13:48 11 question.

15:13:49 12 A. Well in my report I respond to Dr. David,
15:13:53 13 who also is not a filtration expert, his assertions
15:13:56 14 regarding certain data, and -- and so I do have
15:13:59 15 that -- that in my report to the extent I found
15:14:02 16 necessary to rebut what he was saying. But I'm not a
15:14:06 17 filtration expert. I rely upon the filtration expert
15:14:10 18 who was deposed in this litigation, which ends up
15:14:18 19 being very supportive by the company I felt, and so
15:14:22 20 that's -- so it's -- it's indirect support, not
15:14:25 21 personal knowledge of filtration.

15:14:27 22 Q. All right. Couple things I need to unpack
15:14:30 23 from that. First of all, with respect to Dr. David,
15:14:32 24 I'm assuming that from your prior relationship with
15:14:34 25 him you must understand what his level of expertise

15:14:36 1 with filtration is.

15:14:37 2 A. Well as I said in my report, I think I --

15:14:41 3 I know Dr. David, --

15:14:41 4 Q. Uh-huh.

15:14:42 5 A. -- I knew him back at FDA when we were

15:14:46 6 considering members of the GMP committee, --

15:14:49 7 Q. Uh-huh.

15:14:51 8 A. -- so I reviewed his qualifications as an

15:14:52 9 engineer, and background, and I don't recall any

15:14:55 10 evidence of filtration expertise to the degree that

15:14:58 11 you're looking for.

15:14:59 12 Q. Okay. Let's talk about the blanket

15:15:14 13 labeling. It's the final element of opinion four of

15:15:15 14 why you don't have to warn. Do you see what I'm

15:15:18 15 talking about there?

15:15:18 16 A. Opinion four?

15:15:19 17 Q. Well would be not numbered in that way of

15:15:21 18 your dark points, but it will on 73 in the list of

15:15:24 19 things --

15:15:25 20 A. Oh, oh. Okay.

15:15:26 21 Q. And you see where we're talking about point

15:15:28 22 four?

15:15:30 23 A. Yes.

15:15:30 24 Q. Okay. And we had talked about a couple of

15:15:31 25 those things, being the taping design, the filter

15:15:34 1 mitigation. I want to talk about the labeling, the
15:15:37 2 blanket labeling. In what way --

15:15:38 3 What is there about the blanket labeling
15:15:40 4 that deals with airborne contamination?

15:15:41 5 A. Well I think it's the labeling that warns
15:15:44 6 about the need to tape and careful use of the blanket.
15:15:48 7 I think I referenced blanket labeling here somewhere.

15:15:51 8 Q. Okay. So the blanket labeling, you believe
15:15:53 9 that has to do with the taping in terms of --

15:15:55 10 A. Right, proper use of the labeling to -- to
15:15:59 11 prevent -- I --

15:16:00 12 I don't want to misspeak, but I do reference
15:16:02 13 a statement in here somewhere about what the labeling
15:16:05 14 says.

15:16:05 15 Q. Okay.

15:16:05 16 A. And it -- it contributes to the overall
15:16:10 17 mitigation of the risk of airborne contamination.

15:16:13 18 Q. Okay. I want to talk about --

15:16:15 19 You realize that the warnings over time have
15:16:17 20 changed and some have been removed from the Bair
15:16:20 21 Hugger.

15:16:20 22 MS. EATON: Object to the form of the
15:16:21 23 question.

15:16:22 24 A. Say again please.

15:16:22 25 Q. You realize that when it comes to the

15:16:24 1 warnings of the Bair Hugger, they -- some have changed
15:16:27 2 or been removed over time.

15:16:29 3 A. Yes. I -- I have a pretty extensive
15:16:31 4 analysis of the Bair Hugger labeling and of the --
15:16:35 5 what the 200s had versus later models.

15:16:38 6 Q. Okay. So you are aware that, first of all
15:16:41 7 with respect to one of the warnings that was given
15:16:43 8 with an early model Bair Hugger, the 200, it was
15:16:47 9 expressly warned not to use this in an operating room.

15:16:49 10 A. Correct.

15:16:50 11 Q. Okay. That warning does not appear on later
15:16:53 12 Bair Huggers.

15:16:53 13 A. Correct.

15:16:55 14 Q. Okay. You do understand that there is a
15:16:56 15 warning concerning the possibility of airborne
15:16:58 16 contamination should be considered by the user of the
15:17:00 17 device. That has existed on a device.

15:17:04 18 MS. EATON: Object to the form of the
15:17:04 19 question.

15:17:04 20 A. On a device?

15:17:05 21 Q. On a Bair Hugger.

15:17:06 22 A. Say again.

15:17:06 23 Q. Sure.

24 A. Yeah. Sorry.

15:17:07 25 Q. At one point there was a Bair Hugger device,

15:17:11 1 it had a warning on it, that warning advised that the
15:17:16 2 possibility of airborne contamination should be
15:17:16 3 considered by the user.

15:17:18 4 MS. EATON: Object to the form of the
15:17:18 5 question.

15:17:22 6 A. Yeah, I believe so. It was -- it was later
15:17:24 7 dropped, and I explained the -- what I believe there
15:17:30 8 of the circumstances.

15:17:30 9 Q. That was the model 200 that had that
15:17:32 10 warning.

15:17:32 11 A. Correct.

15:17:33 12 Q. And the company did not sell that device or
15:17:37 13 advise people to use that device in an operating room.

15:17:41 14 A. Right. It could have been because of
15:17:44 15 electrical safety hazards, or who knows?

15:17:46 16 Q. You don't know?

15:17:48 17 A. I don't know.

15:17:48 18 Q. Okay. You haven't seen documents relating
15:17:49 19 to why the 200 can't be used in an operating room?

15:17:52 20 A. No. But it -- it could be, you know,
15:17:56 21 various reasons.

15:18:01 22 Q. Now this idea of a warning that appeared on
15:18:07 23 these early devices, not only do you understand that
15:18:09 24 there was a warning on the devices, but there were
15:18:12 25 statements made in the 510(k) recognizing the

15:18:14 1 potential -- the possibility of airborne contamination
15:18:18 2 and that that needed to be mitigated against; correct?

15:18:21 3 MS. EATON: Just let me read the question.

15:18:31 4 Object to the form of the question.

15:18:35 5 Q. Do you remember the question, sir?

15:18:37 6 A. Yes.

15:18:38 7 And you're talking about the summary and the
15:18:41 8 Hall and Zink reference and all that.

15:18:42 9 Q. Uh-huh. Well, and I mean in the summary of
15:18:44 10 safety and effectiveness for Bair Huggers, --

15:18:46 11 A. Yes.

15:18:46 12 Q. -- for 500, the 750, 775, it states that
15:18:52 13 there is -- one of the safety things that is being
15:18:54 14 addressed is the potential for airborne contamination.

15:18:58 15 MS. EATON: Object to the form of the
15:18:58 16 question.

15:19:00 17 A. Well, yeah. There's been a con -- an
15:19:03 18 early-on reference to that with follow-through later,
15:19:07 19 yes.

15:19:08 20 Q. Yeah. There's --

15:19:09 21 In every 510(k) that has appeared since the
15:19:11 22 500, it mentions one of the potential safety issues
15:19:15 23 with this device is the potential for airborne
15:19:17 24 contamination.

15:19:19 25 A. Yeah. I'd have to look at the labeling

15:19:21 1 again, but I think that's the case.

15:19:23 2 Q. Okay. In other words, this isn't an issue
15:19:25 3 that was new to the company. The company knew about
15:19:27 4 the potential of this issue as far back as, say, 1989.

15:19:33 5 A. Well yeah. Early on in the -- in the
15:19:35 6 summary, the early summary, again I refer to the Hall
15:19:39 7 and Zink reference and statement made that -- that
15:19:43 8 there's -- there's some -- some degree of
15:19:45 9 acknowledgment of -- of -- of that potential. Let me
15:19:51 10 put it that way.

15:19:53 11 Q. Okay.

15:19:53 12 A. But it doesn't really define the risk,
15:19:56 13 degree of risk, just says "potential" or something. I
15:20:00 14 forget the wording.

15:20:01 15 Q. Sure. It basically just says there's a
15:20:03 16 potential association between this product and this
15:20:05 17 condition.

15:20:05 18 MS. EATON: Object to the form of the
15:20:06 19 question.

15:20:07 20 A. I'd have to see the exact wording again. I
15:20:09 21 don't recall. I should have memorized it by now, but
15:20:13 22 I haven't.

15:20:13 23 Q. Well in terms of 510(k)s and when a company
15:20:16 24 is listing the potential safety issues that need to be
15:20:19 25 mitigated against, what it is doing is listing certain

15:20:23 1 conditions that have a reasonable, rational
15:20:26 2 association, a logical association with that product.

15:20:32 3 A. Well they're -- they're listing risks,
15:20:36 4 potential risks to whatever degree they are, which are
15:20:43 5 then mitigated, if necessary, to whatever degree
15:20:46 6 necessary. And so, you know, I see the -- I see the
15:20:52 7 early reference that's been carried forward and is the
15:20:57 8 subject of this litigation.

15:21:03 9 Q. I want to talk about your opinion that
15:21:06 10 Arizant appropriately monitored the literature and
15:21:11 11 other sources of information regarding this product
15:21:13 12 and investigated concerns regarding this device.

15:21:17 13 A. Yes.

15:21:17 14 Q. Okay. You hold that opinion in this case.

15:21:19 15 A. Yes, I do.

15:21:22 16 Q. I want to specifically ask you about
15:21:22 17 investigating concerns. Okay?

15:21:25 18 A. Okay.

15:21:25 19 Q. And I want to know each and every thing you
15:21:29 20 were relying on for your opinion that Arizant
15:21:32 21 appropriately investigated the concern of airborne
15:21:34 22 contamination.

15:21:36 23 A. Well that's a simple question, not -- not so
15:21:41 24 quite a simple answer. I had received a -- a lot of
15:21:46 25 documents about Arizant's -- we'll talk about Arizant

15:21:52 1 for a moment -- Arizant's receipts of concerns from
15:21:59 2 hospitals or persons, you know, letters from
15:22:03 3 customers, let me put it that way, interaction with
15:22:07 4 customers, how responsive they were. Of course, you
15:22:14 5 know, what -- what came about later was the -- the
15:22:16 6 Blowing Air Is Risky campaign and their response to
15:22:19 7 that. So what I was looking for was -- was evidence
15:22:26 8 of what sorts of communications were they receiving
15:22:31 9 and how -- how were they responding, and it appeared
15:22:36 10 to me that -- that they were responding to these
15:22:39 11 communications. You may argue not effectively or not
15:22:46 12 correctly, but -- but I saw responsiveness. I saw a
15:22:51 13 rationale for the position they took in their
15:22:53 14 response. Certainly during the course of inspection
15:22:58 15 FDA looked at their -- and these were -- these were
15:23:03 16 comprehensive surveillance inspections, so FDA looked
15:23:05 17 at their postmarket procedures and activities and --
15:23:08 18 and so -- and did not provide adverse comments on
15:23:12 19 them. So there's --
15:23:15 20 In sum, and I've looked at so many companies
15:23:18 21 and how they deal with their devices, and I didn't
15:23:22 22 find them to be -- I found them to be in pretty good
15:23:27 23 shape in regard to response.
15:23:29 24 Q. Okay. Well part of that answer dealt with
15:23:30 25 what the FDA did; right?

15:23:31 1 A. Yes.

15:23:31 2 Q. Okay. And my question was about what did
15:23:34 3 Arizant do to investigate the concerns, and what I
15:23:37 4 have heard is they got letters and they responded to
15:23:40 5 them appropriately.

15:23:41 6 A. Right. And I detail --

15:23:43 7 I couldn't detail everything, every
15:23:45 8 response, because there were so many interactions, so
15:23:48 9 I -- I decidedly picked and choosed, not for any
15:23:55 10 particular reason, but to identify some areas of -- of
15:23:57 11 interaction and response.

15:24:02 12 Q. I want to look at some of the communications
15:24:04 13 the company did receive that you're saying they -- on
15:24:09 14 this issue.

15:24:09 15 A. In my report that I refer to?

15:24:11 16 Q. Something that you've reviewed, yes, sir.

15:24:12 17 A. Okay.

15:24:13 18 Q. And I'm going to refer you -- okay.

15:24:29 19 I'm going to show you a copy of page 38 of
15:24:35 20 plaintiffs' motion for punitive damages, which is
15:24:37 21 something you've reviewed. You see at the top of the
15:24:42 22 page, you see where there's a discussion of an e-mail
15:24:44 23 from Dr. Daniel Sessler?

15:24:47 24 A. Hang on a second.

15:24:48 25 Yes.

15:24:48 1 Q. You know who Dr. Sessler is.

15:24:49 2 A. Yes.

15:24:50 3 Q. Dr. Sessler is somebody the company pays to
15:24:55 4 give them advice on clinical issues; correct?

15:25:00 5 MS. EATON: Object to the form of the
15:25:01 6 question.

15:25:02 7 A. Well that they solicit input on where his
15:25:09 8 outcomes end up or --

15:25:12 9 You know, they'll end up where they end up,
15:25:14 10 pro or con.

15:25:15 11 Q. Right. You understand he's a retained
15:25:17 12 consultant for the company; correct?

15:25:19 13 A. Right. But that --

15:25:20 14 You're implying a bias in his results, and
15:25:23 15 that's not necessary.

15:25:24 16 Q. I'm actually --

15:25:26 17 You're going to see I'm about to imply the
15:25:27 18 opposite, sir. Okay?

15:25:30 19 A. Okay.

15:25:30 20 Q. So we understand he's a paid consultant and
15:25:30 21 he's there to give advice on clinical issues.

15:25:33 22 MS. EATON: Object to the form of the
15:25:34 23 question.

15:25:34 24 Q. Correct?

15:25:34 25 A. Okay. Okay.

15:25:35 1 Q. Okay.

15:25:36 2 A. I understand that he had a relationship.

15:25:38 3 Q. Right. Dr. Sessler had been engaged with
15:25:40 4 e-mails with the company urging them repeatedly to do
15:25:45 5 clinical testing on this issue; correct?

15:25:47 6 MS. EATON: Object to the form of the
15:25:49 7 question.

15:25:51 8 A. I recall interaction with Dr. Sessler and
15:25:53 9 the company on testing.

15:25:55 10 MR. BANKSTON: Let me ask your basis on that
15:25:58 11 one. Ms. Eaton, your basis on that one.

15:26:02 12 MS. EATON: You're mischaracterizing the
15:26:05 13 record.

15:26:05 14 MR. BANKSTON: Okay.

15:26:07 15 Q. Sir, you agree you reviewed this motion;
15:26:10 16 right?

15:26:10 17 A. Yes, I did.

15:26:11 18 Q. Dr. Sessler wrote repeated e-mails to the
15:26:14 19 company; correct?

15:26:15 20 A. I recall looking at the information.

15:26:16 21 But -- but not to forestall the
15:26:20 22 conversation, you also know that in my report there's
15:26:22 23 two areas I defer to others because I didn't fully
15:26:25 24 analyze the information, nor will I do so today, and
15:26:28 25 those two areas were I defer to other witnesses on the

15:26:43 1 plaintiffs' conclusion regarding manipulation of
15:26:44 2 certain research and on plaintiffs' conclusions
15:26:48 3 regarding suppression of testing.

15:26:49 4 Q. Okay.

15:26:50 5 A. So, you know, I didn't comment, I didn't
15:26:53 6 review, and I'm not going to do so today in the spur
15:26:56 7 of the moment.

15:26:57 8 Q. Okay. And I understand --

15:26:58 9 Do you think I'm asking you questions about
15:26:59 10 manipulation of scientific studies?

15:27:01 11 A. Well I think you're getting to that here
15:27:02 12 from what I'm seeing.

15:27:04 13 Q. Okay. Well when we get there, we'll deal
15:27:06 14 with it. Okay? Right now all I'm asking you about is
15:27:09 15 communications to the company --

15:27:10 16 A. Okay.

15:27:11 17 Q. -- about the airborne contamination issue.

15:27:12 18 A. Okay.

15:27:13 19 Q. Dr. Sessler is one of the individuals who
15:27:18 20 communicated to the company about the airborne
15:27:20 21 contamination issue; correct?

15:27:21 22 A. Okay.

15:27:21 23 Q. Is that correct?

15:27:23 24 A. I'm reading what's here.

15:27:24 25 Q. Right. You -- you've read it before; right?

15:27:26 1 A. Well this is an excerpt, so, you know, I'm
15:27:29 2 reading what's here.

15:27:29 3 Q. Well you've read this motion before; right?

15:27:32 4 A. Yes. Yes.

5 Q. Okay.

15:27:32 6 A. I'm reading it here.

15:27:33 7 Q. All right. And you haven't read Dr.

15:27:36 8 Sessler's deposition, is that what you're saying?

15:27:37 9 A. Oh, I'm sure I read his -- at least one or
15:27:40 10 more of his along the way.

15:27:41 11 Q. Okay. This is not new material for you.

15:27:43 12 A. No. No. But this is an excerpt of a quite
15:27:48 13 lengthy deposition I'm sure.

15:27:49 14 Q. And I'm sure if you reviewed this document
15:27:51 15 and there were conclusions made about the case and
15:27:53 16 they were citing deposition testimony, to be thorough,
15:27:57 17 you'd want to go look at that testimony if you had any
15:27:59 18 issues with it.

15:28:00 19 A. I read the testimony, but I didn't, as I
15:28:03 20 said, analyze certain aspects of testimony or --
15:28:06 21 because it -- for whatever reason.

15:28:09 22 Q. Okay. Dr. Sessler told the defendants that
15:28:13 23 their decision not to conduct the clinical studies
15:28:17 24 that were being advised was short-sighted and that
15:28:21 25 there's no way to put any gloss on that. Isn't that

15:28:23 1 what he said?

15:28:23 2 A. Where are you reading from?

15:28:24 3 Q. I'm reading from the bolded part of that top
15:28:26 4 there.

15:28:27 5 A. Oh, I see.

15:28:28 6 Q. That's what Dr. Sessler said?

15:28:29 7 A. I'm assuming this is an accurate quote. I
15:28:38 8 see what's being said.

15:28:39 9 Q. Okay. And if you'll flip to the previous
15:28:40 10 page, on 37, do you see on that page where another
15:28:52 11 e-mail from Dr. Sessler is being discussed?

15:28:53 12 A. You know, these are aspects that I've just
15:28:57 13 talked to you about that I deferred to others on.

15:28:59 14 Q. I don't understand what you mean by that,
15:29:00 15 but I'm going to ask you the questions I want to ask
15:29:02 16 you, and if you want to tell me you have no opinion on
15:29:05 17 them, you can tell me you have no opinion on them.

15:29:07 18 A. I have no opinion.

15:29:07 19 Q. Okay. So in coming to your decision that
15:29:10 20 Arizant acted appropriately in investigating its
15:29:14 21 concerns regarding the device, you did not consider
15:29:16 22 Dr. Sessler's repeated e-mails, including the one page
15:29:22 23 37 in front of you, where he said that their refusal
15:29:22 24 to actually perform these tests seemed like a
15:29:25 25 dangerous strategy. That was not something you

15:29:28 1 reviewed or considered.

15:29:28 2 A. I have no opinion on this specific instance.

15:29:30 3 Q. Right. So these e-mails from Dr. Sessler

15:29:33 4 are things you did not consider in coming to your

15:29:34 5 opinion about what Arizant did in terms of whether it

15:29:36 6 was appropriate in investigating its concerns

15:29:40 7 regarding the device.

15:29:41 8 A. You know, I've said what I've said. I

15:29:43 9 didn't consider them.

15:29:43 10 Q. Thank you.

15:29:44 11 A. I defer to others on this -- those

15:29:48 12 particular two aspects that I mentioned.

15:29:49 13 Q. Well let's -- let's break down those

15:29:51 14 aspects. You understand that there are allegations,

15:29:53 15 and you understand them because you saw them in the

15:29:59 16 punitive damages complaint, --

17 A. Uh-huh. Yes.

18 Q. -- and I'm also --

19 THE REPORTER: "...you understand them

20 because you saw them" --

15:30:00 21 Q. -- in the punitive damage motion, and I'm

15:30:00 22 also assuming that because you made special effort to

15:30:02 23 list them in your report as to something you were not

15:30:06 24 talking about, you saw a discussion of manipulation of

15:30:09 25 a scientific study; correct?

15:30:12 1 A. No, I'm not saying I've seen that. I'm just
15:30:13 2 saying that inasmuch as that there's an allegation to
15:30:15 3 that, I haven't independently assessed that. Whether
15:30:20 4 or not that's within my wheelhouse from a regulatory
15:30:22 5 point of view is another story, you know.

15:30:25 6 Q. It -- it --

15:30:25 7 I mean you -- you knew of it from reading
15:30:28 8 this motion; right? You just didn't invent the phrase
15:30:31 9 "manipulation of scientific studies" out of whole
15:30:35 10 cloth; did you?

15:30:35 11 A. Again, you know, I've cut this manipulation
15:30:38 12 stuff and suppression stuff out of my review.

15:30:41 13 Q. Absolutely. And -- and there's a part of
15:30:42 14 that motion that talks about the manipulation that the
15:30:45 15 plaintiff alleges that the company engaged in with the
15:30:48 16 design and performance of a scientific study; correct?

15:30:54 17 A. Which I said I'm not addressing.

15:30:54 18 Q. And I haven't asked you a single question
15:30:55 19 about that; have I, sir?

15:30:58 20 A. No, sir. This is -- this is all part of it.
15:31:01 21 You can't divorce those issues from what you're
15:31:03 22 reading to me here.

15:31:04 23 Q. You're giving opinions about whether they
15:31:06 24 acted responsibly investigating concerns about the
15:31:09 25 device, and I am asking you about e-mails of an expert

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15:31:12 1 who is urging them to investigate concerns with the
15:31:15 2 device. You don't think that's relevant to your
15:31:17 3 opinion?

15:31:17 4 A. I haven't fully analyzed it. I think that
15:31:20 5 taking things out of context and not fully evaluating
15:31:24 6 all deposition testimony and related facts is -- is
15:31:28 7 biased and -- and, you know, incomplete, so -- so, you
15:31:35 8 know, I can't subscribe to where you're headed on
15:31:38 9 this. All I said is if there's been an allegation of
15:31:42 10 suppression or manipulation, I didn't deal with that.

15:31:44 11 Q. Okay. And then there are also allegations
15:31:46 12 in the second part of that, being the thing you don't
15:31:49 13 want to talk about, as suppression, saying that's not
15:31:52 14 part of your opinion. There is a discussion -- a
15:31:54 15 section of that motion that talks about the
15:31:56 16 company's -- what plaintiff alleges are the company's
15:31:57 17 active efforts to suppress others' research; correct?

15:32:00 18 A. Didn't review it.

19 Q. And that's --

15:32:01 20 A. Didn't analyze it.

15:32:02 21 Q. Exactly. Okay. So we have those two
15:32:04 22 sections, the section about the manipulation of the
15:32:07 23 study and we have the section about the suppression of
15:32:10 24 outside research, and now we have a section in the
15:32:14 25 punitive damage motion about what the company did

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15:32:16 1 itself to investigate the concern. That, you would

15:32:18 2 agree with me, is relevant to your opinions.

15:32:20 3 A. Well inasmuch as it's not related --

15:32:20 4 MS. EATON: Object to the form.

15:32:21 5 A. -- to the manipulation or the suppression.

15:32:25 6 Q. Right. And I'm -- have you -- when I --

15:32:28 7 When Dr. Sessler says I think y'all should
15:32:31 8 do some studies and I'm really urging you to do that,
15:32:34 9 does that have anything to do with manipulation or
15:32:36 10 suppression?

15:32:37 11 A. I think it could be implied.

15:32:38 12 Q. And what is being suppressed exactly?

15:32:40 13 A. "I think you should do studies." Whether or
15:32:42 14 not the company does studies, you know, that if they
15:32:46 15 did not do the studies --

15:32:49 16 I took a -- I took a --

15:32:50 17 Q. That's a surprise.

15:32:51 18 A. I took a pretty broad swath on manipulation
15:32:54 19 or suppression.

15:32:54 20 Q. Okay. So let's just --

15:32:55 21 We're going to go broad swath. In terms of
15:32:57 22 what the company did or did not do to investigate the
15:33:01 23 device, including whether it did or did not perform
15:33:04 24 clinical testing that was advised to it, those are
15:33:08 25 things you do not have opinions on.

15:33:10 1 A. On several of these aspects, no, because I
15:33:14 2 felt it required a rather intensive assessment of the
15:33:20 3 facts and deposition testimony, but also a degree of
15:33:24 4 expertise that I believed I did not possess in order
15:33:28 5 to analyze that.

15:33:42 6 Q. Can you --

15:33:53 7 Now Michelle Hulse Stevens, you know who
15:33:55 8 that is. Do you recall her?

15:33:57 9 A. I remember her deposition.

15:33:58 10 Q. Okay. And she's a medical director with the
15:33:59 11 company?

15:33:59 12 A. Yeah. Yes. Yes.

15:34:01 13 Q. Okay. That's a deposition you reviewed?

15:34:03 14 A. Yes.

15:34:03 15 Q. Okay. And also Ms. Hulse Stevens
15:34:07 16 discussed -- is discussed in this motion; correct?

15:34:09 17 A. I see an excerpt.

15:34:11 18 Q. Correct. In fact, on this very page; right?
15:34:13 19 And there's something coming up about Dr. Michelle
15:34:15 20 Hulse Stevens.

15:34:16 21 A. Right. It starts here.

15:34:17 22 Q. Okay. You understand from her testimony and
15:34:19 23 from this motion that she testified that decisions
15:34:23 24 were previously made at a high level not to pursue
15:34:26 25 clinical research on this topic.

15:34:29 1 A. I don't recall the specific testimony but,
15:34:31 2 you know, there's an excerpt here. Well -- and I see
15:34:36 3 a --

15:34:37 4 "And decisions have been made at the highest
15:34:40 5 levels not to conduct it; correct?

15:34:41 6 "Yes."

15:34:41 7 Q. That was something you reviewed in coming to
15:34:44 8 your opinions in this case.

15:34:45 9 A. I -- I -- I read the depositions. But
15:34:48 10 again, I excluded potential text because there's a
15:34:52 11 particular expertise I think that's necessary to
15:34:53 12 come -- bring to bear on feasibility of those types of
15:34:58 13 studies, meaningfulness of those types of studies,
15:35:01 14 rigor of those types of studies. So a lot of things
15:35:05 15 have to come to bear and a full review of facts from
15:35:09 16 all sides to render a conclusion on this, so I just
15:35:13 17 didn't deal with it.

15:35:14 18 Q. Okay. So in terms of what Arizant did in
15:35:20 19 terms of creating studies, performing studies, which
15:35:24 20 studies they did choose to do, which studies they
15:35:26 21 didn't choose to do and the appropriateness of all of
15:35:29 22 that, that is not something you're here to testify
15:35:31 23 about. That's not --

15:35:32 24 That's somebody else. That's not a
15:35:33 25 Ulatowski opinion.

15:35:34 1 A. Well in regard to these particular facts;
15:35:37 2 for instance, the Sessler studies or other studies
15:35:42 3 that people were suggesting needed to be done, when in
15:35:45 4 fact, you know, who knows what experts are going to
15:35:47 5 say about these things, whether they're feasible,
15:35:51 6 whether they're going to tell you anything in the end
15:35:53 7 or --

15:35:53 8 You know, who knows?

15:35:55 9 Q. There's other doctors besides Dr. Sessler
15:35:58 10 discussed in that motion, too, who have made those
15:36:00 11 recommendations. Do you remember that? For instance,
15:36:02 12 Dr. Parvizi.

15:36:03 13 A. I -- I -- I can't say for sure.

15:36:06 14 Q. Okay. And what about a Dr. Stefan -- and
15:36:09 15 I'm going to butcher this Russian -- but Ianchulev?

15:36:13 16 A. Sounds like part of The Family.

15:36:14 17 No, I don't recall that.

15:36:16 18 Q. Okay. Can you flip to page 40 for me.

15:36:27 19 A. Forty of --

15:36:28 20 Q. The punitive damage motion.

15:36:29 21 A. Okay.

15:36:30 22 Q. Correct. All right. Do you see on page 40
15:36:35 23 a discussion of what has been referred to in many
15:36:38 24 depositions as the war games memorandum?

15:36:41 25 A. I see the term here.

15:36:42 1 Q. You remember that term from several
15:36:44 2 depositions in this case.

15:36:46 3 A. I recall the term.

15:36:47 4 Q. And you've seen that document as well.

15:36:50 5 A. I have --

15:36:51 6 Well, if it's in my reference list, yes.

15:36:53 7 Q. Okay. And --

15:36:54 8 Well you've reviewed the exhibits to
15:36:56 9 plaintiffs' punitive damage motion; correct?

15:36:58 10 A. Yes.

15:36:58 11 Q. Okay. So you've reviewed this document.

15:37:00 12 A. Probably that's the case.

15:37:01 13 Q. Now you under -- you understand in this
15:37:04 14 document they were afraid of someone doing a real
15:37:06 15 study on forced-air warming and contamination. Do you
15:37:08 16 agree with that?

15:37:09 17 A. Well I didn't --

15:37:10 18 Again, I think this is part and parcel of
15:37:14 19 the -- of the information that I stayed away from
15:37:16 20 because it really deserved a very intensive evaluation
15:37:21 21 of -- from not only a microbiological point of view
15:37:25 22 but a clinical point of view -- clinical research
15:37:27 23 point of view on -- on what to make of this all.
15:37:30 24 Because at least I know in my experience at FDA and as
15:37:33 25 a microbiologist, you may -- you may think you can do

15:37:37 1 certain types of studies, but they're -- they're
15:37:39 2 extremely difficult to conduct in the infection
15:37:42 3 control area.

15:37:43 4 Q. Well they're not ask -- talking about in
15:37:45 5 that document whether it can or can't be done, they're
15:37:48 6 making the assumption that if it could be done, that
15:37:51 7 would be not a good thing for the company.

15:37:53 8 MS. EATON: Object to the form of the
15:37:54 9 question.

15:37:54 10 Q. Do you agree with that?

15:37:55 11 A. I can't say neither here nor there because I
15:37:58 12 didn't evaluate that.

15:37:59 13 Q. So when it comes to what the company did to
15:38:02 14 investigate concerns regarding the device, things like
15:38:05 15 their actual discussions on documents about what they
15:38:08 16 would or would maybe not like to do in investigating
15:38:10 17 the device, and their e-mails from their scientific
15:38:13 18 consultants about what to do about investigating or
15:38:16 19 not investigating the device are not things you've
15:38:19 20 considered in this case and do not inform your
15:38:21 21 opinion.

15:38:21 22 MS. EATON: Object to the form of the
15:38:22 23 question.

15:38:22 24 A. Not in regards to these things. As I said,
15:38:25 25 I -- I looked at a great deal of communications from

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15:38:27 1 customers, their interactions with customers, their
15:38:31 2 feedback, their interactions with government agencies
15:38:35 3 in regard to their activities, the focus of
15:38:39 4 inspections and FDA's analysis of their conduct in
15:38:43 5 regard to their postmarket activities, including
15:38:49 6 airborne contamination potential and the company's
15:38:52 7 responsiveness to that, so -- and, you know, that's
15:38:56 8 what I commented on. These -- these -- these other
15:38:59 9 aspects are propositions on studies, interestingly
15:39:07 10 enough after plaintiffs' experts have conducted study
15:39:10 11 after study after study after study, and here we have,
15:39:12 12 "Well they didn't do this study." That's going to be
15:39:15 13 a recurring argument. "Well you didn't do that study.
15:39:18 14 You didn't do that study." Well, I didn't -- I didn't
15:39:21 15 explore that, I didn't research it. And as I said,
15:39:24 16 I -- I think you need a particular expertise to see
15:39:27 17 whether this is hogwash or whether there's some merit
15:39:30 18 here.

15:39:30 19 Q. Okay. And that's not expertise you have.

15:39:32 20 A. No. Not that I would claim to have, no.

15:39:35 21 Q. Okay. Would you make any arguments about
15:39:45 22 whether any particular studies were applicable to any
15:39:48 23 particular Bair Hugger device?

15:39:50 24 MS. EATON: Object to the form of the
15:39:51 25 question.

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15:39:55 1 A. Well there's -- there's the rub, I suppose,
15:39:58 2 because in many of the studies the -- the application
15:40:02 3 of the -- or the methodologies and the results are --
15:40:05 4 are in question and how relevant it is to the actual
15:40:09 5 performance of the Bair Hugger device in a real-world
15:40:13 6 situation, so, you know, that's -- that's a part of
15:40:17 7 the conten -- contention between both sides. One side
15:40:21 8 yes, we have information, we don't have evidence of
15:40:24 9 this or that, we've done studies; the other side says,
15:40:28 10 well, we've done studies and we find it. So, you
15:40:33 11 know, it's --

15:40:33 12 There's two sides on it.

15:40:33 13 Q. I -- I need to make something clear that I
15:40:37 14 think may help you answer some of my questions, and
15:40:40 15 it's come up a couple of times. I'm not real
15:40:43 16 concerned about what one side might say or what
15:40:46 17 another side might say, I'm extremely concerned about
15:40:50 18 what you are going to say.

15:40:50 19 A. Yes. And I told you what -- what I would
15:40:52 20 probably say.

15:40:52 21 Q. All right. So what I still am not clear on
15:40:54 22 is: Are you going to be giving any opinions about
15:40:56 23 whether any particular study is directly applicable to
15:41:02 24 any particular model of Bair Hugger?

15:41:02 25 MS. EATON: Object to the form of the

15:41:02 1 question.

15:41:02 2 A. If it's not in my opinions, it's not in my

15:41:06 3 opinions --

4 Q. Well --

15:41:06 5 A. -- unless a question provokes some answer.

15:41:09 6 Q. Let's look at page 37.

15:41:10 7 A. Okay.

15:41:11 8 MS. EATON: Of what?

15:41:12 9 MR. BANKSTON: Of his report.

15:41:17 10 A. Okay.

15:41:18 11 Q. And you're --

15:41:19 12 One of the opinions you give here, do you

15:41:21 13 see where you're talking about the Zink and Hall

15:41:23 14 publication?

15:41:23 15 A. Yes.

15:41:25 16 Q. Okay. One of those is the argument that the

15:41:26 17 Zink and Hall publication and poster are not

15:41:28 18 applicable to the model 750 due to a change in media

15:41:31 19 and airflow is incorrect. That's your opinion?

15:41:35 20 A. Well that was provoked by Dr. David's

15:41:36 21 opinion.

15:41:37 22 Q. Every opinion is provoked by Dr. --

15:41:40 23 You're here to rebut Dr. David's --

24 A. Right.

15:41:43 25 Q. -- opinions; right?

15:41:43 1 A. Right.

15:41:44 2 Q. So that's your opinion.

15:41:45 3 A. Right. That's a statement that I have, yes.

15:41:47 4 Q. Okay. First of all, do you understand the

15:41:49 5 differences between those two devices?

15:41:51 6 A. Yes.

15:41:51 7 Q. Okay. Tell me what they are.

15:41:52 8 A. The --

15:41:54 9 Well the airflows are different, for

15:41:56 10 example, the filter being different ultimately.

15:42:00 11 Q. How is the airflow different?

15:42:01 12 A. More so in the 750.

15:42:05 13 Again, the -- the filter ultimately is being

15:42:09 14 changed to be different, the other mechanical --

15:42:12 15 electromechanical aspects of the device being

15:42:15 16 different. I'd have to look in the 510(k) again to

15:42:18 17 see what those differences were, but I mean those are

15:42:22 18 a couple differences.

15:42:25 19 Q. Okay. Now if the 5 -- if the -- excuse me.

15:42:31 20 If --

15:42:31 21 The 750, if it turns out, contrary to what

15:42:35 22 you believe right now, that the 750 is putting

15:42:39 23 particulates into the air, assume for me for the

15:42:41 24 moment that is something that is an opinion, is that

15:42:43 25 an opinion that you're prepared to rebut today in this

15:42:46 1 deposition?

15:42:49 2 MS. EATON: Object to the form of the
15:42:50 3 question.

15:42:50 4 A. My opinions are what my opinions are. I --
15:42:53 5 I -- I don't understand your question.

15:42:53 6 Q. My question is: If somebody makes the
15:42:56 7 argument, "Model 750 is putting particulates into the
15:43:00 8 operating room air," do you have a rebuttal opinion
15:43:02 9 for that?

15:43:03 10 A. Do you mean during the trial if someone
15:43:06 11 makes that statement? I -- I guess I still don't get
15:43:09 12 it.

15:43:09 13 Q. Well if I made it right now. I'm making
15:43:10 14 it, I'm making it in the room this very moment. Do
15:43:14 15 you have an opinion on that?

15:43:14 16 MS. EATON: Hold on. Let me -- let me read.

15:43:23 17 THE WITNESS: Are we holding on here?

15:43:24 18 MR. BANKSTON: Yes, we're waiting for an
15:43:26 19 objection.

15:43:26 20 MS. EATON: Yes, just a second. I'm just
15:43:27 21 going to read it.

15:43:35 22 Okay.

15:43:36 23 MR. BANKSTON: Answer.

15:43:38 24 A. You know, I'm sorry, you're going to have to
15:43:41 25 read the question again.

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15:43:41 1 Q. Okay. Let's ask it this way. We got to
15:43:49 2 reboot the opinion, which is the opinion that -- was,
15:43:51 3 if I'm saying it right now, "The Bair Hugger 750
15:43:56 4 causes more particulates, is introducing particulates
15:43:59 5 into an operating room," that's my contention I just
15:44:01 6 threw into the air, do you have rebuttal opinions that
15:44:05 7 you're qualified to give about whether that opinion is
15:44:08 8 true or not?

15:44:09 9 MS. EATON: Object to the form of the
15:44:10 10 question.

15:44:10 11 A. I'd have to look at your foundation for that
15:44:12 12 statement. I'd have to assess it.

15:44:14 13 Q. Okay. Let's look at --

15:44:16 14 MR. BANKSTON: Can we have this marked.

15:44:25 15 (Ulatowski Exhibit 8 was marked for
15:44:26 16 identification.)

15:44:27 17 (Discussion off the stenographic record.)

15:44:29 18 BY MR. BANKSTON:

15:44:39 19 Q. All right, Mr. Ulatowski, you've seen this
15:44:41 20 document in a couple of depositions and in motions
15:44:44 21 with the red and black; right?

15:44:46 22 A. Yes, it looks familiar.

15:44:48 23 Q. Okay. This is --

15:44:50 24 You're familiar with Al Van Duren.

15:44:53 25 A. Yes.

15:44:53 1 Q. Okay. Al Van Duren manages clinical affairs
15:44:57 2 for the company for many years; correct?

15:44:59 3 A. Yes.

15:44:59 4 Q. Okay. And he was communicating with Dr.
15:45:02 5 Michelle Hulse Stevens. Do you remember that?

15:45:03 6 A. Okay. Yes, I do now.

15:45:05 7 Q. And do you remember that Al Van Duren made
15:45:07 8 some notes about a study by Reed?

15:45:09 9 A. I'm trying to recollect the context here.

15:45:11 10 Q. Okay. If you will flip the page, you'll see
15:45:15 11 that there's red and black comments.

15:45:22 12 A. Okay.

15:45:23 13 Q. All right. And do you remember the
15:45:25 14 deposition testimony about how there are comments in
15:45:28 15 black from Mr. Van Duren and responses in red from Dr.
15:45:32 16 Michelle Hulse Stevens?

15:45:33 17 A. I -- I am recalling that.

15:45:34 18 Q. Okay. One of the things I want you to go
15:45:39 19 down and look is on the very last page on number
15:45:43 20 seven.

15:45:44 21 A. Okay.

15:45:44 22 Q. Do you see where Mr. Van Duren says, "The
15:45:47 23 apparently greater particulate emission from the 750
15:45:51 24 may simply be a function of its airflow, which is 81
15:45:56 25 percent greater than the model 505E." Do you see that

15:45:59 1 statement?

15:45:59 2 A. I see it.

15:46:00 3 Q. Do you have any reason to dispute Mr. Van

15:46:02 4 Duren on that statement?

15:46:04 5 A. Nor to support it without evaluating what

15:46:10 6 he's basing this on.

15:46:14 7 I notice that there's not a comment from

15:46:17 8 Hulse Stevens.

15:46:18 9 Q. Yes. She didn't have anything to say to

15:46:20 10 this one.

15:46:21 11 This one here, he's talking just simply

15:46:23 12 about the function of airflow; right?

15:46:25 13 MS. EATON: Object to the predicate.

15:46:28 14 A. Well it's a simple statement, --

15:46:31 15 Q. Uh-huh?

15:46:31 16 A. -- isolated statement. I -- I don't know

15:46:33 17 what to make of it, to tell you the truth.

15:46:36 18 Q. You don't think what?

15:46:37 19 A. I don't know what to make of it, to tell you

15:46:39 20 the truth, the 10 words, 15 words here.

15:46:42 21 Q. All right. Let's go back up to number one.

15:46:49 22 You see where he says, "The assertion that old filters

15:46:51 23 are more efficient than newer ones is correct."

15:46:59 24 A. Yes.

15:46:59 25 Q. Yes. And that's true; isn't it?

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15:47:02 1 A. The M20 was -- had a lower efficiency than
15:47:06 2 the M10, if that -- if that's your point.

15:47:09 3 Q. I would think that that would mean that the
15:47:11 4 old effi -- old filters are more efficient than the
15:47:15 5 new ones; right?

15:47:16 6 A. Correct.

15:47:17 7 Q. Okay. So that statement he gives is
15:47:19 8 correct; right?

15:47:25 9 A. Yes. Yes.

15:47:26 10 Q. Okay.

15:47:27 11 A. Both .2 micron filters, but nonetheless
15:47:30 12 different efficiencies.

15:47:31 13 Q. What does a .2 micron filter mean? What is
15:47:34 14 that?

15:47:37 15 A. It's a particulate size that the particular
15:47:38 16 filter media is designed to block at -- at some degree
15:47:41 17 of efficiency. I -- there's diff --

15:47:44 18 There's various types of filters. I used
15:47:49 19 cellulosic .2 micron filters in the lab. There's
15:47:54 20 different filters.

15:47:54 21 Q. That -- that term doesn't really mean a lot
15:47:55 22 until you know the efficiency at that particle size;
23 right?

15:47:58 24 A. What do you mean, it doesn't mean a lot? It
15:47:59 25 means a lot. .2 micron --

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15:48:00 1 You can buy filters at different micron
15:48:03 2 levels for filtering. I used various filters of
15:48:07 3 different sizes for filtering solutions, bacterial
15:48:09 4 solutions versus viral -- virus solutions versus other
15:48:16 5 types of -- of pharmaceuticals in the area that I --
15:48:19 6 that I worked.

15:48:20 7 Q. All right. You would agree with me --
15:48:23 8 I guess what you're saying is let's say
15:48:27 9 there's a filter and it, at two mic -- at .2 microns,
15:48:29 10 filters out 95 percent of the particulate matter at .2
15:48:32 11 microns. We can call that a .2 micron filter. That's
15:48:35 12 fine; right?

15:48:35 13 A. Sure.

15:48:36 14 Q. Let's say we have a filter at .2 microns, it
15:48:40 15 filters out one percent of --

15:48:41 16 Ninety-nine percent of .2 micron particles
15:48:44 17 get through this filter. Is that a .2 micron filter?

15:48:44 18 A. It's still a .2 micron filter, and its
15:48:47 19 efficiency changes over time as -- as the filter
15:48:50 20 become used, so the efficiency actually increases over
15:48:53 21 time.

15:48:53 22 Q. Okay. So you're saying that you would
15:48:54 23 have --

15:48:55 24 You think it is appropriate and honest to
15:48:58 25 describe a filter that only filters out one percent of

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15:49:01 1 two micron filters, you're comfortable with calling
15:49:04 2 that a .2 micron filter.

15:49:06 3 A. Right. It's clear that that's -- that's the
15:49:07 4 primary specification. The efficiency is another
15:49:12 5 characterization of the product's performance. So
15:49:14 6 yes, if -- if -- if indeed that's the filter
15:49:19 7 manufacturer's, based on standard testing and design,
15:49:22 8 yes, if that's their finding, that's their finding.

15:49:25 9 Q. You -- you've read Dr. Robert Crowder's
15:49:27 10 deposition; right?

15:49:28 11 A. Yes.

15:49:28 12 Q. Okay. He works for Pentair, --

15:49:30 13 A. Yes.

15:49:31 14 Q. -- not 3M. Right?

15:49:32 15 A. Correct.

15:49:32 16 Q. Okay. And you understand that Dr. Crowder
15:49:34 17 doesn't have a definition or no -- treat the term ".2
15:49:39 18 micron filter" as meaningful. That was a term
15:49:42 19 invented by the company. Do you understand that?

15:49:45 20 A. No, that's -- that's -- that's incorrect. I
15:49:48 21 used to use Millipore filters that had definitely
15:49:49 22 different micron designations, so, you know, I can't
15:49:52 23 subscribe to that.

24 Q. And he --

15:49:52 25 A. He might -- he might be used to the

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15:49:55 1 particular filters he's familiar with. I used various
15:49:58 2 other types of filters that were also designated.

15:50:02 3 Q. Okay. But at the end of the day, say we
15:50:05 4 have a filter that at .2 microns is almost entirely
15:50:09 5 ineffective at filtering out .2 microns, only gets one
15:50:14 6 percent or .5 percent, .1 of one percent at two
15:50:18 7 microns, that's still a .2 micron filter in your view?

15:50:21 8 A. It still has the potential for filtering .2
15:50:24 9 micron particulates. You'll find that, for example,
15:50:28 10 in --

15:50:28 11 I mean let's look at something common, the
15:50:31 12 house filters. You'll find various designations of
15:50:34 13 filtration size as well as efficiency, and people will
15:50:38 14 buy mostly the least efficient but yet particularly --
15:50:45 15 particulate-rated filters there are because -- because
15:50:50 16 of cost.

15:50:50 17 Q. Okay. Let's go to the next sentence in that
15:50:53 18 statement, which is, "The change to new filter
15:50:56 19 material was dictated by engineering concerns prior to
15:51:00 20 widespread appreciation of the importance of
15:51:04 21 particulates discharged by the warming unit." Do you
15:51:08 22 agree with that?

15:51:09 23 A. I agree that's what's stated here.

15:51:11 24 Q. Well let me ask it this way: Do you have
15:51:14 25 any reason to dispute Mr. Van Duren about the change

15:51:18 1 of filter materials and what the company did or did
15:51:21 2 not know?

15:51:21 3 A. Yeah. I wouldn't rely on only Mr. Van
15:51:27 4 Duren. I think I -- I'd be evaluating in total, to
15:51:31 5 the degree I could, all the experts in the company,
15:51:34 6 those that were involved in the design of the
15:51:38 7 products, the rationale for the changes, what was
15:51:40 8 known, what wasn't known. I found company testimony
15:51:44 9 that some testimony is not entirely -- doesn't
15:51:50 10 entirely speak to the whole picture.

15:51:53 11 Q. Okay. So in this case you believe Mr. Van
15:51:54 12 Duren is wrong, or do you not have an opinion?

15:51:56 13 A. I'm not saying he's wrong. I think this
15:51:58 14 is --

15:51:58 15 If this is what he said, this is what he
15:52:00 16 believed, but it's not necessarily the case.

15:52:03 17 Q. That's what Mr. Zgoda, the project leader of
15:52:06 18 the Bair Hugger 750, said as well, too; right?

15:52:08 19 A. I'd have to look at all that.

15:52:09 20 Q. We will.

15:52:10 21 A. I mean you're throwing this in front of me.

15:52:12 22 Q. Don't worry, we will.

15:52:14 23 The last line is the Michelle Hulse Stevens
15:52:16 24 line, the medical director; correct?

15:52:18 25 A. Yes.

15:52:18 1 Q. Do you remember that from her testimony?

15:52:19 2 A. Yes.

15:52:19 3 Q. Okay. And she says, "This implies then that
15:52:21 4 the 750 does not have a filtration efficiency that
15:52:25 5 adequately mitigates parti -- particulates in the air
15:52:28 6 coming out after filtration." Do you see that
15:52:30 7 statement?

15:52:30 8 A. I see it.

15:52:31 9 Q. Okay. Now in your view, is Dr. Michelle
15:52:35 10 Hulse Stevens wrong here?

15:52:37 11 A. Well she's making a simple statement. You
15:52:40 12 know, I'd have to review her entire deposition and
15:52:45 13 other information. What I'm saying is I -- I can't
15:52:45 14 draw a lot of conclusions from reading these couple
15:52:49 15 sentences.

15:52:49 16 Q. You did read her deposition; correct?

15:52:51 17 A. I did.

15:52:51 18 Q. And you read plaintiffs' punitive damage
15:52:53 19 motion; correct?

15:52:54 20 A. Right.

15:52:54 21 Q. And you've read Dr. Yadin David's report;
15:52:58 22 correct?

15:52:58 23 A. Right. And I -- I --

15:52:59 24 Q. And your opinions are meant to address
15:53:01 25 those -- all of those things; right?

15:53:03 1 A. Right.

15:53:03 2 Q. Okay. So I'm wondering, what else do you
15:53:06 3 need to review to have an opinion about Dr. Michelle
15:53:09 4 Hulse Steven's statement?

15:53:11 5 A. My -- my impression from my review of all
15:53:14 6 that information is I don't think this adequately
15:53:18 7 expresses the view of the company.

15:53:19 8 Q. Okay. Okay. I'd like you to take
15:54:06 9 plaintiffs' punitive damage motion in front of you and
15:54:09 10 flip it to page nine. I'm actually sorry, the
15:54:13 11 numbering ought to be seven. Forget --

15:54:14 12 At the bottom of the page it will say seven.

15:54:16 13 A. Okay. I'm taking this one and looking at
15:54:19 14 page what?

15:54:20 15 Q. Seven.

15:54:21 16 A. Seven.

15:54:22 17 MS. EATON: Hold on. Let me get it.

15:54:26 18 A. Hopefully this is what you're asking me to
15:54:28 19 look at, but okay.

15:54:29 20 Q. Okay.

15:54:29 21 MS. EATON: Just a moment, because I have to
15:54:31 22 find my place, please.

15:54:54 23 MR. BANKSTON: Are we ready to proceed?

15:54:55 24 MS. EATON: Yes.

15:54:56 25 THE WITNESS: Yes.

15:54:56 1 Q. On page seven, you see there's some

15:55:00 2 discussion by a gentleman named Karl Zgoda; right?

15:55:04 3 A. Right. There -- there's an extraction from

15:55:06 4 his deposition.

15:55:06 5 Q. Right. A quotation from his deposition;

15:55:08 6 right?

15:55:08 7 A. Yes.

15:55:08 8 Q. A deposition you reviewed.

15:55:09 9 A. Yes.

15:55:10 10 Q. A deposition that was attached to this

15:55:12 11 motion; correct?

15:55:13 12 A. Yes.

15:55:14 13 Q. A deposition that was cited and discussed in

15:55:16 14 the same language in Dr. David's report; correct?

15:55:18 15 A. Correct.

15:55:19 16 Q. Okay. Karl Zgoda was the project leader for

15:55:23 17 the 750; right?

15:55:30 18 A. I think so.

15:55:30 19 Q. Okay. He was asked, "In validating the 750,

15:55:34 20 what testing did you rely on?"

15:55:36 21 And he answered, "As far as validating the

15:55:38 22 device?"

15:55:38 23 And he was re-asked, "As far as this

15:55:41 24 prevention of airborne contamination, what testing did

15:55:44 25 you rely on to assure us that the unit was safe?"

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15:55:47 1 Mr. Zgoda stated, "I would say I'm not aware
15:55:50 2 of any verification testing that was done internal to
15:55:54 3 the company to verify this."

15:55:56 4 Do you have any reason to believe Mr. Zgoda
15:55:59 5 was wrong about that before the release of the model
15:56:01 6 750?

15:56:02 7 A. Well I -- I see his response. He says "I'm
15:56:08 8 not aware."

15:56:09 9 Q. Uh-huh.

15:56:10 10 A. Well there's -- there's many people involved
15:56:15 11 in the evaluation, so -- and they're relying upon also
15:56:19 12 supplier evaluations of components. So, you know, I
15:56:23 13 don't know if I'd -- I'd -- I'd say this is entirely
15:56:25 14 accurate, but I see what he's saying.

15:56:28 15 Q. Okay. And you're not disputing what he's
15:56:30 16 saying, right, that Mr. Zgoda did testify that he was
15:56:34 17 not aware of any verification testing done internal at
15:56:37 18 the company. Right?

15:56:37 19 A. Well I see what he's saying.

15:56:39 20 Q. Right. In terms of supplier relationships
15:56:41 21 that you just discussed and outside testing by
15:56:44 22 suppliers, you've read Dr. Crowder's deposition, the
15:56:46 23 representative of Pentair; correct?

15:56:49 24 A. Yes.

15:56:49 25 Q. And you understand that they did no testing

15:56:51 1 for internal contamination for airborne contamination
15:56:55 2 issues.

15:56:56 3 A. Well they were evaluating the performance of
15:56:58 4 the filter --

15:56:58 5 Q. Sure.

15:56:59 6 A. -- under various test conditions.

15:57:01 7 Q. Well do -- do you have understanding that --
15:57:03 8 that Pentair knew the efficiency of the M20 filter and
15:57:08 9 knew what it was, had done testing?

15:57:11 10 A. I don't recall the testimony, but I do
15:57:13 11 recall some of the test results. And -- and now --
15:57:17 12 now you're --

15:57:18 13 I don't want to stick my neck out in regard
15:57:20 14 to filter testing because I'm not a filter expert.

15:57:23 15 Q. Okay. But you have given the test -- your
15:57:27 16 opinions in your report that the filter for the Bair
15:57:29 17 Hugger is adequate; right?

15:57:32 18 A. I didn't say it in those terms.

15:57:36 19 Q. Okay. So that's not an opinion you're going
15:57:36 20 to be giving, that you won't be addressing clinical
15:57:38 21 adequacy -- adequacy of the Bair Hugger's filter.

15:57:41 22 A. No. Where this all began I think is in my
15:57:44 23 response to Dr. David's contention that Hall and Zink
15:57:50 24 data have no relevance whatsoever to the 750.

15:57:52 25 Q. Okay. And another thing that you had

15:57:54 1 testified about was how the design process, as
15:57:57 2 encapsulated in the design history file and perhaps
15:58:01 3 other documents and other testimony, from that you
15:58:02 4 were able to determine that the risk of airborne
15:58:05 5 contamination had been adequately considered and
15:58:06 6 addressed; correct?

15:58:09 7 A. I don't think those are my exact words.

15:58:11 8 Q. Would you agree with that statement?

15:58:17 9 A. Well that would take me into territory that
15:58:20 10 I didn't opine on, I believe.

15:58:22 11 Q. Okay. You stated your opinion was the
15:58:34 12 design history files of the Bair Huggers model 505 and
15:58:37 13 750 provided reasonable assurance of the safety and
15:58:39 14 effectiveness of the design of these devices, and what
15:58:41 15 I want to know from that opinion: Are you making any
15:58:45 16 specific claims about the filters being adequate?

15:58:49 17 A. Well certainly the design history file as I
15:58:52 18 found that, based upon the regulatory requirements and
15:58:56 19 my experience evaluating design history files,
15:58:59 20 contained the elements necessary to be addressed in
15:59:03 21 the design of a -- of a device. So I know you
15:59:06 22 concentrate on -- on filtering efficiency and that's
15:59:10 23 part -- partly a supplier expectation, but certainly
15:59:17 24 was significant testing on electrical safety, on other
15:59:21 25 aspects of the device that were, I think, disregarded

15:59:24 1 by Dr. David. So, you know, to say there was no
15:59:29 2 safety testing is -- is completely incorrect.

15:59:32 3 As far as airborne contamination testing,
15:59:35 4 that's why I referred to the contention on the Hall
15:59:38 5 and Zink article, because the act of filtering in a
15:59:43 6 filtered environment has value. To what degree, it
15:59:48 7 can be contentious -- contentious as to what degree it
15:59:51 8 has value, but the fact of filtering has value, and
15:59:56 9 that was -- I call it proof of principle that, you
16:00:05 10 know, the filtering is -- filtering has an effective
16:00:08 11 result in regard to airborne contamination. So we can
16:00:12 12 argue about the degree of filtering, airborne
16:00:15 13 contamination degrees, where the air is going, that's
16:00:18 14 all part of an argument that's broader than what I'm
16:00:22 15 able to opine on.

16:00:23 16 Q. Okay. Now one of those that you just
16:00:25 17 discussed is Hall; right?

16:00:27 18 A. Yes.

16:00:27 19 Q. That's a poster presentation.

16:00:28 20 A. Yes.

16:00:28 21 Q. Not peer reviewed or anything like that.

16:00:30 22 A. Correct.

16:00:31 23 Q. Okay. The other one is Zink and Iaizzo;
16:00:34 24 correct?

16:00:34 25 A. Correct.

16:00:37 1 Q. That's something Dr. Augustine paid for;
16:00:37 2 right?

16:00:37 3 A. Right. And he's paid for other studies too.
16:00:41 4 Yes.

16:00:41 5 Q. Uh-huh. And you've had some problems with
16:00:44 6 him paying for studies; don't you?

16:00:45 7 A. I don't -- I don't fundamentally have a
16:00:48 8 problem paying for studies. I think that's been the
16:00:50 9 course of industry practice.

16:00:53 10 Q. Okay.

16:00:53 11 A. So I don't think that fundamental aspect is
16:00:54 12 arguable.

16:00:55 13 Q. Now that study was conducted on eight
16:00:57 14 volunteers and --

16:00:58 15 A. Correct, at that point in time. It -- it is
16:01:00 16 what it is.

16:01:02 17 Q. Now that test, the company did not conduct
16:01:07 18 that test before it starts selling the product; did
16:01:10 19 it?

16:01:10 20 A. No. They didn't conduct the test, no.

16:01:13 21 Q. And in fact that test didn't occur until the
16:01:17 22 product was already on the market and being sold and
16:01:19 23 there had been significant investment in it.

16:01:22 24 MS. EATON: Object to the form of the
16:01:23 25 question.

16:01:23 1 A. Well the paper was published, it was in the

16:01:25 2 510(k), so, you know --

16:01:28 3 Q. Zink and Iaizzo was not in the original --

4 THE REPORTER: I'm sorry?

5 MR. BANKSTON: I'm sorry.

16:01:35 6 Q. Zink and Iaizzo was not in the 500 series

16:01:35 7 510(k); is it?

16:01:36 8 A. No, not in the 500.

16:01:36 9 Q. Okay. And that's the first product to be

16:01:37 10 used in an operating room.

16:01:39 11 A. Correct.

16:01:39 12 Q. Okay. I just want to point to you in

16:01:41 13 plaintiffs' punitive damage motion -- I know you

16:01:45 14 talked about how it was probably not a good idea to

16:01:48 15 rely on Mr. Zgoda in isolation. One person probably

16:01:51 16 can't remember everything, right, that happened in a

16:01:53 17 company?

16:01:53 18 A. Correct. They have particular

16:01:55 19 responsibilities and duties and -- and, you know,

16:02:00 20 sometimes the left hand doesn't know what the right

16:02:02 21 hand's doing --

16:02:03 22 Q. Right.

16:02:03 23 A. -- in an organization.

16:02:04 24 Q. So you have this gentleman, who was the

16:02:07 25 project leader of the Bair Hugger 750, who presumably

16:02:07 1 knows a great deal about the Bair Hugger 750 but maybe
16:02:10 2 doesn't know everything, so you'd agree with me it's
16:02:13 3 probably a good idea to see what others have to say as
16:02:16 4 well.

16:02:16 5 A. Sure.

16:02:17 6 Q. Okay. If you look further down the page
16:02:19 7 you'll see there's testimony from Mr. Van Duren;
16:02:22 8 correct?

16:02:22 9 A. Where are we at now?

16:02:22 10 Q. Same page. Do you see the next --

16:02:26 11 A. Okay, I see it.

16:02:27 12 Q. Okay?

16:02:27 13 A. Uh-huh.

16:02:28 14 Q. And Mr. Van Duren was asked, before 750 was
16:02:31 15 ever released and sold and used on a patient, what was
16:02:33 16 done to ensure that the change in air output had no
16:02:36 17 adverse effect on airborne contamination issues, and
16:02:38 18 Mr. Van Duren, the clinical director of the company
16:02:41 19 says, "Well to my knowledge there were no tests that
16:02:44 20 looked at airborne particulate levels with the new
16:02:49 21 device before it went on the market."

16:02:49 22 That's something that you saw and reviewed
16:02:50 23 before you came to your opinions; correct?

16:02:52 24 A. I read the deposition testimony.

16:02:53 25 Q. Correct.

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16:02:56 1 I'd like to refer you to the previous page.

16:03:01 2 Do you see in the bolded print type where the CEO of

16:03:05 3 the company, Gary Maharaj, testified that he could not

16:03:08 4 recall any testing carried out during the development

16:03:10 5 of the Bair Hugger 500 series to support the assertion

16:03:14 6 that airborne particles were not a problem? Do you

16:03:16 7 remember that testimony from Mr. Maharaj?

16:03:19 8 A. Well this is -- I mean this isn't a quote.

16:03:25 9 Oh, hang on a second. What is the quote

16:03:28 10 here?

16:03:31 11 Q. It's the part in quotation marks.

16:03:33 12 Do you remember that testimony?

16:03:35 13 A. Yeah. But part of this is not a quotation,

16:03:38 14 so it's a characterization of his testimony.

16:03:41 15 Q. Uh-huh. Did you look into that?

16:03:44 16 A. Yeah, I looked at the DHFs, I looked at the

16:03:48 17 510(k)s, I looked at the evaluations done by the

16:03:54 18 suppliers, knowledge of the par -- particular filters

16:04:00 19 being made and their efficiencies, and of the testing

16:04:03 20 and all the -- so on -- on both sides --

16:04:07 21 Q. I was --

16:04:09 22 A. -- to assess, you know, this very same

16:04:10 23 issue.

16:04:10 24 Q. I was a little bit imprecise with my

16:04:14 25 pronouns by saying "that," "Did you look into that?"

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16:04:18 1 What I meant by that is you say that this is a partial
16:04:20 2 quote and partial characterization. Did -- did you
16:04:22 3 look at Mr. Maharaj's testimony on this issue?

16:04:25 4 A. I read his deposition.

16:04:27 5 Q. Okay. So do you remember this particular
16:04:28 6 statement of his?

16:04:29 7 A. I don't particularly remember this specific
16:04:32 8 statement.

16:04:33 9 Q. Do you have any feeling today of what Mr.
16:04:37 10 Maharaj's opinion or statement or testimony was
16:04:40 11 regarding whether the company had carried out testing
16:04:41 12 for airborne contamination on the Bair Hugger before
16:04:44 13 it was released for surgery?

16:04:45 14 A. Which one?

16:04:47 15 Q. Before it was released for surgery, so that
16:04:49 16 would be the 500; correct?

16:04:50 17 A. I'd have to look at all the other test data
16:04:58 18 and -- and background information, --

16:04:59 19 Q. Okay.

16:05:02 20 A. -- the literature, see what they make of
16:05:03 21 airborne contamination in the --

16:05:04 22 Q. What about --

16:05:05 23 A. -- in the hospital setting.

16:05:07 24 Q. You reviewed Teri Woodward-Sides'
16:05:10 25 deposition; right?

16:05:11 1 A. Whose?

16:05:11 2 Q. Teri Woodwick-Sides.

16:05:13 3 A. That -- that does ring a bell, yes.

16:05:15 4 Q. You've actually read two of her depositions;

5 right?

16:05:18 6 A. I believe so.

16:05:19 7 Q. Okay. She's the vice president of product

16:05:20 8 development. Do you remember that now?

16:05:21 9 A. I don't recall her title.

16:05:23 10 Q. Okay. Would you disagree with me that she

16:05:26 11 testified that no product testing had ever recurred

16:05:28 12 with regard to the Bair Hugger and airborne

16:05:30 13 contamination?

16:05:30 14 A. I'd have to evaluate that again. I didn't

16:05:34 15 opine on it.

16:05:34 16 Q. If she said that, was that something you

16:05:35 17 re -- included when reviewing and forming your

16:05:38 18 opinions?

16:05:39 19 MS. EATON: Object to the form of the

16:05:40 20 question.

16:05:40 21 A. I'd have to review her deposition to see --

16:05:42 22 again, to see what relevance. I didn't

16:05:44 23 particularly -- I didn't cite her deposition testimony

16:05:49 24 in any evaluation of the DHFs.

16:05:52 25 Q. You're familiar with regulatory compliance

16:05:54 1 manager David Westlin?

16:05:55 2 A. Yes.

16:05:56 3 Q. Okay. You read his deposition?

16:05:57 4 A. Yes.

16:05:58 5 Q. Read two of his depositions in fact.

16:06:00 6 A. Probably.

16:06:02 7 Q. Okay. Would you dispute with me that he
16:06:02 8 testified that the company has not done any internal
16:06:04 9 testing with regard to airborne contamination?

16:06:08 10 A. I don't recall his testimony in regard to
16:06:10 11 that, so --

16:06:11 12 Q. Wouldn't you think it was important, sir,
16:06:13 13 when reviewing the testimony of the witnesses in this
16:06:16 14 case, primarily the executive corporate witnesses who
16:06:18 15 made decisions on the Bair Hugger, to understand what
16:06:21 16 they did in terms of testing and evaluating airborne
16:06:26 17 contamination risks? That's an important thing; isn't
16:06:28 18 it?

16:06:28 19 A. I -- I addressed Dr. David's report, I
16:06:35 20 addressed what I viewed as relevant to the opinions
16:06:37 21 that I created in my report, so --

16:06:41 22 Q. All of -- all of this that we've just
16:06:44 23 discussed was in Dr. David's report; correct?

16:06:46 24 A. Not necessarily, no.

16:06:48 25 MS. EATON: Object to the form of that

16:06:48 1 question.

16:06:48 2 A. No.

16:06:48 3 Q. Okay.

16:06:49 4 A. I don't think so. No. Some of it was, not
16:06:51 5 all of it.

16:06:54 6 Q. I want to talk about the filter a little
16:08:21 7 bit, about -- okay. First of all, let's talk about
16:08:24 8 the change in filter.

16:08:26 9 There was, between the 500 series and 700
16:08:29 10 series, a change in filter; correct?

16:08:31 11 A. Yes.

16:08:32 12 Q. Okay. Your opinion is that the FDA was
16:08:33 13 informed by means of a letter that the model 750 would
16:08:38 14 include a .2 micron filter just as the model 505 did.

16:08:43 15 A. Correct.

16:08:44 16 MS. EATON: Object to the form of the
16:08:45 17 question.

16:08:46 18 A. And not -- and not a HEPA filter.

16:08:47 19 Q. Correct, it's not a HEPA filter.

16:08:49 20 And you say that Augustine Medical never
16:08:54 21 claimed in that letter that the model 750 would have
16:08:57 22 the same filter efficiency as the model 505.

16:09:01 23 A. I believe I say that.

16:09:02 24 Q. Okay. Now in that letter --

16:09:05 25 Let me go ahead and get you a copy of that.

16:09:14 1 MR. BANKSTON: And Dick, let's re-mark that
16:09:16 2 over the old exhibit.

16:09:28 3 (Ulatowski Exhibit 9 was marked for
16:09:31 4 identification.)

16:09:31 5 BY MR. BANKSTON:

16:09:39 6 Q. All right. In this document, Ulatowski
16:09:43 7 Exhibit 9 --

16:09:44 8 MS. EATON: Did you give me a copy?

16:09:45 9 MR. BANKSTON: He has it right next to him.
16:09:45 10 I don't know --

16:09:47 11 He's looking at it.

16:09:47 12 MS. EATON: No. Did you give me a copy?

16:09:49 13 MR. BANKSTON: Oh, no. Here you go.

16:09:51 14 MS. EATON: Thank you.

16:09:52 15 (Document handed to Ms. Eaton.)

16:09:56 16 Q. Sir, I'd like to ask you about Exhibit 9.

16:09:58 17 A. Right. The reason I'm -- I'm pausing is I'm
16:10:01 18 turning to my opinion to see precisely what I said
16:10:05 19 about it.

16:10:05 20 Q. You see in Exhibit 9 that this is a letter
16:10:09 21 that the F -- that was written to the FDA concerning
16:10:12 22 the change of filter in the Bair Hugger.

16:10:15 23 A. Yes.

16:10:16 24 Q. Okay. This letter tells the FDA that
16:10:21 25 instead of a plan to improve the filter from what it

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16:10:25 1 was to a HEPA filter, now instead the company is going

16:10:30 2 to use our current filter characteristics; correct?

16:10:36 3 A. Hang on, let me just read further.

16:10:53 4 Current filter characteristics is what it

16:10:58 5 says.

16:10:58 6 Q. Yes. That's what I'm asking you. They told

16:10:58 7 the FDA we plan, instead of improving the filter, to

16:11:01 8 use our current filter characteristics; correct?

16:11:04 9 A. Yes.

16:11:05 10 Q. Okay. And then do you see down -- down in

16:11:09 11 the later paragraph there's a portion where it

16:11:12 12 describes some differences? Do you see that?

16:11:15 13 A. Yes.

16:11:16 14 Q. And in the des --

16:11:18 15 What it says is, "The description of this

16:11:20 16 filter will be the same, but the physical size will be

16:11:23 17 slightly smaller."

16:11:24 18 A. Yes.

16:11:25 19 Q. Correct?

16:11:25 20 A. Yes.

16:11:26 21 Q. Can you point me to anything in this

16:11:28 22 document that would inform the FDA, that would allow

16:11:33 23 them to know in any way, shape or form that the

16:11:35 24 performance characteristics of that filter were

16:11:38 25 changing?

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16:11:40 1 A. Well I think -- I think, first of all, that
16:11:43 2 it says the filter characteristics. Are they
16:11:46 3 referring to .2 micron only? If that's the case, then
16:11:49 4 there's no misstatement.

16:11:51 5 Q. There's -- and there's --

16:11:53 6 Well that's not my question. You understand
16:11:54 7 I did not ask you that.

16:11:56 8 A. Just let me preface that.

16:11:58 9 Q. Okay.

16:11:59 10 A. And the second part is you have to
16:12:01 11 understand even -- even if it was the intention of the
16:12:03 12 company to have the exact same filter efficiency,
16:12:09 13 exact same efficiency as the 505, the M10, as soon as
16:12:15 14 that 510(k) was cleared by FDA, Arizant could change
16:12:20 15 those specifications over night and market a different
16:12:23 16 product without another 510(k).

16:12:26 17 Q. In fact, they did that with the 505; didn't
16:12:28 18 they? They changed the filter in the 505.

16:12:30 19 A. Right. And they -- they changed it with the
16:12:33 20 750.

16:12:33 21 Q. And --

16:12:34 22 Well they made a new 510(k) for the 750;
23 right?

16:12:37 24 A. Not for the filter characteristics.

16:12:39 25 Q. Well I mean I'm not trying to mince words

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16:12:43 1 with you here, but there was a new 510(k) for that
16:12:45 2 product; right?

16:12:46 3 MS. EATON: I'm sorry, can -- I didn't --

16:12:48 4 MR. BANKSTON: Correct?

16:12:49 5 MS. EATON: I did not hear what you said.

16:12:53 6 MR. BANKSTON: There's a new 510(k) for that
16:12:53 7 product.

16:12:53 8 MS. EATON: Which product?

16:12:54 9 MR. BANKSTON: The 750.

16:12:55 10 A. Well there was a new 510(k) for the 750.

16:12:57 11 Q. Right. There was a new 510(k) for the 750.

16:13:02 12 A. Right. Yes.

16:13:02 13 Q. There was not --

16:13:02 14 There's never been a new 510(k) for the 505.

16:13:04 15 A. No.

16:13:04 16 Q. Okay. They both had the same change.

16:13:06 17 A. Right.

16:13:07 18 Q. Okay. The --

16:13:09 19 What I'm asking you is: In this document,
16:13:11 20 is there anything in this document that indicates to
16:13:14 21 the FDA in any way whatsoever that the efficiency or
16:13:17 22 performance of that filter is being reduced?

16:13:22 23 A. It's not stated here.

16:13:23 24 Q. No.

16:13:24 25 A. But it didn't have to be stated to FDA.

16:13:26 1 Q. Again, my question is, just to go down a
16:13:28 2 trail here if we can find from this document, is there
16:13:31 3 anything --

16:13:31 4 Did the FDA have any idea that the filter
16:13:34 5 was being reduced in its performance?

16:13:39 6 A. Not from this correspondence or any other
16:13:41 7 correspondence that I've seen. But it's my contention
16:13:45 8 and my opinion in my report that's not the type of
16:13:46 9 change that's reportable to FDA in any case.

16:13:49 10 Q. Okay. Now irrespective of whether that
16:13:52 11 change was reported to the FDA, if the company's going
16:13:54 12 to change a safety component on their product, they
16:13:56 13 need to validate and make sure that change is safe.

16:13:59 14 A. Well they need to assess the change and
16:14:01 15 whether -- whether they need to validate.

16:14:03 16 Q. Okay. What was done? What was done to
16:14:06 17 assess the change?

16:14:08 18 A. Well they looked at the characteristics of
16:14:11 19 the device, the improved performance of the device
16:14:13 20 because of airflow -- airflow characteristics, so they
16:14:18 21 were increasing the benefit of the device. They
16:14:20 22 understood that the efficiency was different at a
16:14:23 23 certain micron level, which probably, in my opinion,
16:14:29 24 would be irrelevant at the higher micron level.

16:14:33 25 But --

16:14:34 1 And so they -- they did a -- what
16:14:38 2 essentially is a -- a scientific paper evaluation of
16:14:41 3 the difference in the products.

16:14:42 4 Q. Okay. First of all, with respect to your
16:14:48 5 opinion you just gave about not even relevant at
16:14:51 6 higher micron levels, what we were talking -- what
16:14:54 7 you're talking about is the typical size of airborne
16:14:58 8 bacteria; correct?

16:14:58 9 A. Right.

16:14:59 10 Q. Okay. That's not something you're offering
16:15:00 11 opinions on; right?

16:15:01 12 A. No, I'm not.

16:15:02 13 Q. Okay. Dr. Ho, are you familiar with him?

16:15:05 14 A. Yes.

16:15:05 15 Q. Yeah. He offered opinions on that. Have
16:15:07 16 you read his report?

16:15:07 17 A. No, I don't think I have seen his report.

16:15:09 18 Q. Have you seen his testimony that I took?

16:15:11 19 A. Recently?

16:15:12 20 Q. Yeah, --

16:15:13 21 A. No.

16:15:13 22 Q. -- in the last little bit.

16:15:14 23 A. I have not seen it.

16:15:15 24 Q. Okay. You would defer to him on the size of
16:15:20 25 airborne particular matter.

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16:15:21 1 A. Yes. He's more -- he's certainly more up to
16:15:24 2 date, more expert.

16:15:25 3 Q. Okay.

16:15:26 4 A. Right.

16:15:28 5 Q. Now first of all, you admit the filter is a
16:15:33 6 safety-related component; right?

16:15:37 7 Well let me -- let me rephrase that. I'm
16:15:40 8 sorry. Let me take that back.

16:15:41 9 The filter is specifically identified as a
16:15:43 10 safety component in the 510(k) summary of safety and
16:15:46 11 effectiveness for both the model 500 and the model
16:15:50 12 750.

16:15:50 13 MS. EATON: Object to the form of the
14 question.

15 A. For 500, yes. 750, I'm not -- I don't
16:15:55 16 recall for certain.

16:15:56 17 Q. Okay. I'll -- I'll -- I'll represent to
16:15:59 18 you, I don't know if you remember it or not, but the
16:16:00 19 only difference between the two safety and
16:16:03 20 effectiveness statements which occurred with the
16:16:04 21 filter is a slight changing in the wording. You
16:16:09 22 understand the filter is still mentioned in the 510(k)
16:16:10 23 for the 750?

16:16:11 24 A. Oh, sure. And, you know, I know in the
16:16:12 25 specifications list in the labeling it points to a .2

16:16:15 1 micron filter. Doesn't say anything about efficiency.

16:16:17 2 Q. Right. And that part is there to mitigate

16:16:19 3 the possibility of airborne contamination.

16:16:20 4 MS. EATON: Object to the form of the

16:16:21 5 question.

16:16:22 6 A. Well there's different opinions on that. I

16:16:25 7 think opinions on whether it's there --

16:16:28 8 I think it has a -- a couple functions based

16:16:30 9 on deposition testimony.

16:16:31 10 Q. Let's -- let's just do it then with what it

16:16:34 11 says in the 510(k). In the 510(k) for both of those

16:16:36 12 devices, the 500 and the 750, that is identified

16:16:40 13 specifically as something that is used to mitigate the

16:16:43 14 possibility of airborne contamination.

16:16:46 15 A. Right. And -- and --

16:16:49 16 I want to make sure that, you know, we have

16:16:51 17 terminology right here. When -- when you say

16:16:53 18 "contamination," you know, there's a difference

16:16:56 19 between airborne particulates versus airborne

16:17:02 20 contamination versus airborne-induced/caused potential

16:17:09 21 fomites in a surgical field. So, you know,

16:17:14 22 particulates, yeah. Whether that translates to

16:17:17 23 infectious particles, that's another story.

16:17:19 24 Q. All right. The -- the 510(k) doesn't say

16:17:20 25 anything about particles, does it, just says airborne

16:17:23 1 contamination of the surgical room.

16:17:24 2 MS. EATON: If we're going to talk about two
16:17:26 3 different 510(k) summaries of safety and
16:17:30 4 effectiveness, can we please have them in front of us
16:17:31 5 rather than asking for a memory test?

16:17:33 6 MR. BANKSTON: If he's got them, he's got
7 them. But I mean we're just talking about the very
8 thing that --

16:17:35 9 THE WITNESS: I don't have it with me.

16:17:35 10 MS. EATON: That's fine. I would -- I
16:17:38 11 would --

16:17:38 12 MR. BANKSTON: Then he can --

16:17:38 13 Then his answer can be, simply enough, "I do
16:17:39 14 not know."

16:17:39 15 MS. EATON: That's fine.

16:17:40 16 MR. BANKSTON: "I don't have it in front of
16:17:41 17 me."

16:17:41 18 MS. EATON: I'm -- I'm simply asking you as
16:17:43 19 a matter of fairness, rather than having him try to
16:17:48 20 memorize completely two statements from among the
16:17:48 21 documents he has reviewed, if you intend to ask him
16:17:51 22 very detailed questions about the language in those
16:17:53 23 documents, I think it would be appropriate and fair
16:17:54 24 for you to place them in front of him.

25 MR. BANKSTON: All right. Well let's just

1 ask --

16:17:57 2 MS. EATON: You will decide if you're going
16:17:57 3 to do it or not.

16:17:58 4 MR. BANKSTON: Right.

16:17:59 5 Q. Let's just ask you the simple question,
16:18:01 6 because at the end, it all gets done.

7 Do you admit the filter is a safety
8 component and identified as such to the federal
9 government?

16:18:05 10 That's not a complicated, get-down-in-the-
16:18:08 11 weeds opinion; right? It's identified as a safety
16:18:10 12 component.

16:18:10 13 MS. EATON: Object to the form of the
16:18:11 14 question.

16:18:11 15 A. Well I -- I think early on there's some --
16:18:15 16 it's alluded to. I don't think in subsequent 510(k)s
16:18:19 17 it's necessarily an affirmative statement.

16:18:22 18 MR. BANKSTON: Let's go off the record for
16:18:23 19 just a second.

16:18:26 20 THE REPORTER: Off the record, please.

16:18:28 21 (Recess taken.)

16:27:12 22 BY MR. BANKSTON:

16:27:22 23 Q. All right, Mr. Ulatowski, if 3M informed the
16:27:29 24 FDA that the filter was a safety component, played a
16:27:33 25 safety function, and then decided to change that

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16:27:36 1 filter and its media in some respect, you would agree
16:27:40 2 with me that the company has an obligation to assess
16:27:42 3 that change and determine that it is safe.

4 MS. EATON: Object to the form of that
16:27:53 5 question.

16:27:53 6 A. I would be more -- more general to say when
16:27:55 7 you change a component, there should be some assess --
16:27:59 8 assessment on the effect on the device.

16:28:02 9 Q. So really if anything changes on the device,
16:28:05 10 we need to assess whether it -- it affects safety from
16:28:09 11 a responsible manufacturer.

16:28:10 12 A. To -- to whatever degree is necessary in the
16:28:12 13 view of the company.

16:28:15 14 Q. What if the company decides that nothing is
16:28:18 15 necessary to do any assessment?

16:28:21 16 A. Well I need to know the rationale, I
16:28:23 17 suppose. But, you know, it's possible that happens
16:28:26 18 certainly.

16:28:26 19 Q. Okay. And that's -- you'd agree that's
16:28:34 20 particularly true of safety functions. Safety pieces
16:28:37 21 of the device need to be looked at fairly carefully
16:28:39 22 whenever they're changed.

16:28:40 23 A. It -- it depends what the change is. It may
16:28:42 24 be within a range of change that really doesn't have a
16:28:47 25 particular impact.

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16:28:48 1 Q. Okay. I -- I want to ask you about if you
16:28:53 2 had a filter you were selling to the public on your
16:28:56 3 device and it filters out 95 percent of .2 micron
16:29:01 4 particles, they're calling it a .2 micron filter, and
16:29:05 5 then you change that filter and it now filters out
16:29:07 6 less than half of the .2 micron particles, is it your
16:29:11 7 testimony today that it is still an honest
16:29:14 8 representation to say to customers and the government
16:29:17 9 that that filter has the -- is -- is a two -- .2
16:29:21 10 micron filter with the same filter characteristics?

16:29:25 11 MS. EATON: Object to the form of the
16:29:26 12 question.

16:29:27 13 A. Yeah. The specifications haven't changed.
16:29:29 14 That's -- that's what was listed in the device. Would
16:29:31 15 it be material to the customer to know that? Well
16:29:38 16 I -- I don't think so. I -- I think people are
16:29:40 17 getting too hung up on this filter-efficiency issue.

16:29:44 18 Q. You -- you certainly know that orthopedic
16:29:47 19 surgeons are highly sensitive and concerned about
16:29:51 20 particulate matter in their operating rooms; correct?

16:29:54 21 A. I can't speak for all orthopedic surgeons.
16:29:58 22 Some may not be all that concerned at all. I don't
16:30:00 23 know.

16:30:01 24 Q. Well you've read the International
16:30:03 25 Consensus; right?

16:30:03 1 A. Yes.

16:30:03 2 Q. And they were very concerned about
16:30:05 3 particles; correct? That's some of their opinions in
16:30:11 4 that consensus.

16:30:12 5 A. That's what they addressed. But I can't
16:30:14 6 speak for all physicians or -- or generally for
16:30:17 7 orthopedic surgeons as a whole.

16:30:17 8 Q. Okay. I want to talk a little bit about the
16:30:21 9 2009 facility inspection.

16:30:23 10 A. Sure.

16:30:23 11 Q. Okay. So part of that, you understand, is
16:30:29 12 that FDA had an inspector show up to the facility,
16:30:32 13 conduct interviews with employees; correct?

16:30:34 14 A. Correct.

16:30:35 15 Q. One of those employees being David Westlin,
16:30:37 16 the regulatory compliance director.

16:30:39 17 A. Sure.

16:30:39 18 Q. That's fairly usual. That's somebody you
16:30:43 19 would talk to in one of those kind of inspections.

16:30:45 20 A. Absolutely.

16:30:45 21 Q. Okay. After the inspection is done there's
16:30:48 22 a report prepared; correct?

16:30:50 23 A. That's correct.

16:30:51 24 Q. Okay. And in that report -- you understand
16:30:56 25 that in that report the report states what is not

16:31:00 1 true, that the Bair Hugger has a HEPA filter.

16:31:03 2 A. Correct.

16:31:03 3 Q. Okay. You understand that after an FDA
16:31:12 4 inspection it sends its findings to the manufacturer.

16:31:16 5 A. That should be done. It -- it's actually
16:31:18 6 not frequently done.

16:31:20 7 Q. Okay. Are you familiar with reports known
16:31:22 8 as 483 inspectional observations?

16:31:24 9 A. Yes.

16:31:24 10 Q. Okay. Those were provided to the company;
16:31:28 11 correct?

16:31:28 12 A. Yes, those are provided at the conclusion of
16:31:30 13 the inspection.

16:31:30 14 Q. Okay. And the company actually had an
16:31:32 15 opportunity to respond and did respond in the company
16:31:35 16 by letter; correct?

16:31:36 17 A. That's the normal industry practice, yes.

16:31:38 18 Q. Right. And they make any comments they may
16:31:40 19 have on the inspectional observations.

16:31:42 20 A. On 483, yes.

16:31:44 21 Q. Okay. Nowhere during that process, whether
16:31:47 22 it was during the 483 process, the letters that were
16:31:51 23 being written or upon publication of the report, no
16:31:54 24 action was taken immediately upon the issuance of that
16:31:58 25 report to correct that statement to the FDA.

16:32:00 1 MS. EATON: Object to the form of the
16:32:01 2 question.

16:32:03 3 A. I'm not aware of any correction being made.

16:32:05 4 Q. At any time?

16:32:07 5 A. At any time.

16:32:08 6 Q. You have not been provided with a letter
16:32:11 7 dated December of 2016 that was addressed to the
16:32:15 8 Minneapolis field office of the FDA?

16:32:17 9 A. In regard to the 2009 inspection?

16:32:20 10 Q. Uh-huh.

16:32:20 11 A. I don't think I've seen that.

16:32:21 12 Q. So you didn't know in 2016 that the company
16:32:24 13 wrote saying that they're going to clarify that
16:32:27 14 statement and it doesn't have a HEPA filter.

16:32:29 15 A. Well I may have to take that back, but I --
16:32:33 16 I just didn't recall them addressing that point in the
16:32:36 17 prior inspection.

16:32:36 18 Q. Okay. So between 2009 and 2016 they did
16:32:40 19 nothing to correct that assertion in that report and
16:32:44 20 in 2016 they did. You understand that?

16:32:46 21 A. Okay.

16:32:48 22 MS. EATON: Object to the form of the
16:32:49 23 question. The original letter did not come in 2009.

16:32:52 24 Q. Well the inspection was in 2009; correct,
25 sir?

16:32:55 1 A. Yes.

16:32:57 2 Q. Okay. Thank you.

16:32:57 3 Have you ever seen a company send a letter
16:33:12 4 by priority overnight delivery seven years after an
16:33:16 5 inspection report correcting information within it?
16:33:19 6 Is that something you've ever seen?

16:33:21 7 A. Could I please see the letter just to
16:33:23 8 refresh my memory?

16:33:23 9 Q. I actually don't --

16:33:25 10 I thought you might have it. I thought you
16:33:27 11 knew about this letter.

16:33:28 12 A. I don't have it.

16:33:28 13 Q. We can get one. I mean I'm just wondering,
16:33:31 14 not with regard to this letter, but have you ever seen
16:33:35 15 a letter sent to the FDA correcting a inspection
16:33:38 16 report seven, eight, nine years after it happened?

16:33:42 17 A. I've seen corrections to inspection reports,
16:33:43 18 I've seen corrections to 510(k)s years after the fact,
16:33:48 19 so nothing would surprise me.

16:33:49 20 Q. Okay. You will agree with me that Arizant
16:33:51 21 knew that in a report dealing with airborne
16:33:56 22 contamination risk their filter was incorrectly
16:34:00 23 described as a HEPA filter and for six years they did
16:34:02 24 nothing to correct that.

16:34:06 25 A. Well what -- it --

16:34:08 1 It was not corrected.

16:34:11 2 MS. EATON: Object to the form of the
16:34:12 3 question.

16:34:19 4 Q. Did you happen to review --

16:34:21 5 I know you reviewed plaintiffs' motion for
16:34:23 6 punitive damages. Did you happen to review
16:34:26 7 defendants' response to that motion?

16:34:31 8 A. I don't think I did.

16:34:31 9 Q. Okay. Okay. And maybe that's where we got
16:34:36 10 it up. I didn't -- I didn't actually --

16:34:38 11 I thought maybe it was part of the punitive
16:34:40 12 damages report. My mistake. It was actually in
16:34:44 13 exhibits to defendants' response on punitive damages.

16:34:45 14 As far as the exhibits go that defendant may
16:34:48 15 have offered in response to punitive damages, you
16:34:53 16 don't think that's something you reviewed?

16:34:53 17 A. Not --

16:34:54 18 No. I don't recall it offhand.

16:34:55 19 Q. Okay. Now I'm going to ask you to assume
16:35:08 20 that from 2009 to 2016 Arizant did nothing to correct
16:35:16 21 the observation in the inspection report that there
16:35:18 22 was a HEPA filter. All right? You can make that
16:35:20 23 assumption with me. Do you think that it is proper
16:35:24 24 for a manufacturer to allow that information to
16:35:27 25 continue, knowing that it's not true?

16:35:30 1 A. Well I think I actually addressed this in
16:35:34 2 my -- my report, and -- and I believe I said, well,
16:35:38 3 looking at the -- looking at the particular focus of
16:35:41 4 the inspection and the observations, it wasn't
16:35:44 5 particularly germane to the -- to the topic.

16:35:47 6 Q. You --

16:35:48 7 A. There were a couple issues to be addressed,
16:35:50 8 air -- certainly airborne contamination, the MDRs. I
16:35:53 9 think the focus came out to be what -- what do you do
16:35:57 10 with MDRs and with the so-called CAPAs, C-A-P-As,
16:36:01 11 and -- and that -- and that's where it fell out.
16:36:06 12 And -- and so that -- that --

16:36:10 13 I'm not sure what importance that really had
16:36:13 14 in the end result.

16:36:14 15 Q. It had importance enough to be sent in an
16:36:17 16 overnight letter for priority delivery to the FDA in
16:36:23 17 December of 2016; correct?

16:36:23 18 A. Well they did that, but -- but in -- in
16:36:26 19 thinking back, would that have changed anything in
16:36:28 20 regard to how I responded -- the agency responded to
16:36:33 21 that inspection, and -- and I think not.

16:36:40 22 Q. You -- I can't recall if you said "yes" or
16:36:42 23 "no." Actually, let me just check.

16:36:48 24 I think you have Exhibit 1 in front of you
16:36:52 25 there, Exhibit 2, which is your reliance list. Will

16:36:54 1 you check that for me?

16:36:55 2 A. Oh, yeah. Yes. There it is.

16:37:00 3 Q. Okay. Can you tell me, did you read Dr.

16:37:04 4 Sessler's deposition?

16:37:05 5 A. Deposition?

16:37:06 6 Q. Yes, sir.

16:37:06 7 A. Well, this should tell the tale. It's not
16:37:23 8 listed here.

16:37:24 9 Q. Okay.

16:37:27 10 A. Oh, yes, it is.

16:37:28 11 Q. Okay. And what date do you have for that?

16:37:30 12 A. May 28, 2015.

16:37:33 13 Q. Okay. So that would be a deposition that
16:37:35 14 was conducted in the prior -- your prior engagement.

16:37:38 15 A. Yes, it appears so.

16:37:39 16 Q. Okay. So you have not reviewed Dr.
16:37:41 17 Sessler's testimony in -- in the consolidated case.

16:37:45 18 A. Evidently not.

16:37:46 19 Q. Okay. So you wouldn't be able to tell me
16:37:48 20 what kind of filter Daniel Sessler thought was on the
16:37:53 21 machine when reaching his conclusions about it, about
16:37:56 22 the adequacy of it.

16:37:56 23 A. I have no knowledge of his testimony.

16:37:58 24 Q. Okay. One more question about the filter.

16:38:16 25 You recall seeing the e-mails discussing that we

16:38:22 1 currently offer sub-HEPA filtration?

16:38:25 2 A. Yes.

16:38:25 3 Q. Okay.

16:38:26 4 A. Yes.

16:38:26 5 Q. And -- and this e-mail that you discussed

16:38:31 6 about the --

16:38:32 7 The e-mail says a reduction in efficiency --

16:38:35 8 a reduction in the efficiency of the filter may

16:38:37 9 require some action, but because of the way it's

16:38:40 10 described as a sub-HEPA filter, the basis of our

16:38:43 11 safety claims is a sub-HEPA filter, as long as you're

16:38:48 12 still sub-HEPA, you're still in that categorization.

16:38:50 13 Would you agree with that?

16:38:52 14 MS. EATON: Object to the form of the

16:38:53 15 question.

16:38:53 16 A. I comment on that sub-HEPA filtration

16:38:56 17 aspect. I'm not sure if this is what you're speaking

16:38:58 18 to, but I certainly --

16:38:59 19 Dr. David, I know, referred to a -- a

16:39:01 20 portion of a conversation, and I expanded with the

16:39:03 21 full conversation to give it context, and the issue

16:39:09 22 was, well, we had sub -- sub-HEPA in the -- sub-HEPA

16:39:13 23 in the prior device and we have sub-HEPA in this

16:39:15 24 device, so -- so hey. You know, I guess that was what

16:39:19 25 my point is.

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16:39:19 1 Q. Right. So I guess what -- what you had said
16:39:21 2 was a plausible interpretation of this document is
16:39:25 3 that sub-HEPA filtration is needed for new devices.
16:39:28 4 You got to have sub-HEPA because that's what we had in
16:39:31 5 our product.

16:39:31 6 A. Sub-HEPA is -- right. Otherwise, we might
16:39:36 7 not --

16:39:37 8 I think the point was we might have to
16:39:39 9 assess with data or something like that.

16:39:40 10 Q. All right. A filter that stops zero percent
16:39:43 11 of particles up to 50 microns, that's sub-HEPA;
16:39:49 12 correct?

16:39:49 13 A. Zero percent of particles up to 50 percent.

16:39:53 14 Q. Fifty microns.

16:39:56 15 A. Fifty microns.

16:39:57 16 Q. That's sub-HEPA.

16:39:58 17 A. Yeah. I'm -- I'm thinking about the HEPA
16:40:02 18 categorization. I'm not sure that's quite right,
16:40:06 19 but -- but, you know --

16:40:07 20 Q. Well let's -- let's talk about the HEPA
16:40:11 21 characterization, about what its specifications are.

16:40:13 22 You would agree with me that a high-
16:40:17 23 efficiency particulate filter, a HEPA filter, is able
16:40:18 24 to filter out 99.97 percent of particles at .3
16:40:23 25 microns. Do you agree that's about right?

16:40:25 1 A. Yes, with -- with, you know, a given test
16:40:28 2 methodology and airflow, for example, and of course
16:40:33 3 assuming no bleed-through around the filter.

16:40:35 4 Q. Now a filter that can filter out one percent
16:40:39 5 of particles 5,000 micron size, that's sub-HEPA.
16:40:43 6 That's below HEPA's efficiency.

16:40:46 7 A. Yes.

16:40:46 8 Q. And that would be fine to use on the Bair
16:40:48 9 Hugger?

16:40:48 10 A. That would be --

16:40:50 11 Excuse me?

16:40:50 12 Q. You could --

16:40:50 13 In other words, you don't have to do any
16:40:52 14 sort of testing or any sort of thing special because
16:40:54 15 that's a sub-HEPA filter. If you put that filter on
16:40:57 16 the Bair Hugger, you're good because it's sub-HEPA.

16:40:59 17 MS. EATON: Object to the form of the
16:41:01 18 question.

16:41:01 19 A. Well I -- I think that the idea of
16:41:02 20 filtration at the .2 micron level is -- is an
16:41:10 21 interesting aspect of -- of the Bair Huggers. I
16:41:12 22 think -- as I alluded to, I think people are getting
16:41:16 23 perhaps too caught up in this efficiency issue in
16:41:19 24 regard to the filtration, filtration in a filtered
16:41:23 25 environment. And when you -- when you change the

16:41:27 1 efficiency, what -- what are your criteria established
16:41:33 2 that you made any clinical difference? That's a very
16:41:36 3 tough thing to -- to prove. Very tough thing.

16:41:39 4 MR. BANKSTON: Objection, non-responsive.

16:41:41 5 Q. My question is: Is a filter that filters
16:41:44 6 out one percent of particles of 5,000 micron size,
16:41:48 7 that is a sub-HEPA filter; correct?

16:41:50 8 A. Anything below HEPA is a sub-HEPA filter.

16:41:53 9 MS. EATON: Let me object to the form of
16:41:54 10 that question.

16:41:54 11 Q. Any --

16:41:55 12 Basically, any filter under the sun, any one
16:42:00 13 of them that doesn't live up to the HEPA certification
16:42:03 14 is going to be a sub-HEPA filter.

16:42:06 15 MS. EATON: Object to the form of that
16:42:07 16 question.

16:42:07 17 A. To the absurd point, extreme, yes, but
16:42:10 18 that's not where the company was going.

16:42:12 19 Q. Well your plausible interpretation, sir, is
16:42:16 20 that sub-HEPA filtration is all that's needed for
16:42:18 21 these new devices; right?

16:42:19 22 A. Yes, within the -- just as within the
16:42:22 23 parameters of how the company considered the standard
16:42:24 24 that they were trying to meet.

16:42:26 25 Q. What standard were they trying to meet?

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16:42:28 1 A. Ultimately, they -- they gravitated to the
16:42:31 2 MERV 14 standard because of the operating room
16:42:33 3 characteristic standard that existed, and so the
16:42:38 4 filters they were using both met the same MERV 14
16:42:40 5 standard.

16:42:41 6 Q. Your testimony, though, has been -- and at
16:42:44 7 least your opinions in your report is there's not a
16:42:46 8 standard for filtration on a forced-air warming
16:42:49 9 device; right?

16:42:50 10 A. Right. Not specifically for a forced-air
16:42:53 11 warming device.

16:42:53 12 Q. Okay.

16:42:54 13 A. But what I'm saying is there are standards
16:42:57 14 for filtration in an OR, so in the absence of specific
16:43:03 15 standards the industry moves to and utilizes whatever
16:43:08 16 might be germane to the issue, in this case MERV
16:43:11 17 standards, for example.

16:43:12 18 Q. All right. And so we're --

16:43:13 19 A. And I wouldn't argue with that, that usage.

16:43:16 20 Q. Right. So we're talking about these MERV 14
16:43:19 21 standards for use approved in surgeries. Do you have
16:43:21 22 any idea what the standard is for filtration when
16:43:24 23 performing an ultraclean orthopedic surgery?

16:43:26 24 MS. EATON: Object to the form of the
16:43:27 25 question.

16:43:27 1 A. I don't recall the -- the -- the standard.

16:43:29 2 But, --

16:43:30 3 Q. Okay.

16:43:30 4 A. -- you know, the point is people are making
16:43:32 5 some to-do about moving from 10 to 20, and it made no
16:43:37 6 difference within the parameters of the MERV 14
16:43:41 7 standard.

16:43:46 8 Q. You can't tell me that all MERV 14 standards
16:43:49 9 are safe in orthopedic procedures; can you?

16:43:52 10 A. Well I think that --

16:43:53 11 MS. EATON: Object to the form of the
16:43:55 12 question.

16:43:55 13 A. -- that goes beyond my expertise in
16:43:57 14 filtration, and, you know, I'd leave that to those who
16:44:02 15 are better suited to assess that.

16:44:03 16 Q. Okay. Some of your opinions are regarding
16:44:06 17 the alternative designs identified by Dr. David;
16:44:09 18 correct?

16:44:09 19 A. Correct.

16:44:09 20 Q. Okay. Your opinion is that these devices
16:44:13 21 have some different features than the Bair Hugger
16:44:15 22 devices and that they have different features that
16:44:19 23 present new hazards; correct?

16:44:21 24 A. Yes.

16:44:22 25 Q. Okay.

16:44:22 1 A. Yes.

16:44:23 2 Q. Are you familiar with the Mistral-Air
16:44:25 3 system?

16:44:25 4 A. Yes. That's one of the examples he gave.

16:44:27 5 Q. Okay. What different features does it have?

16:44:30 6 A. You know, I recall pulling up the
16:44:33 7 Mistral-Air website and looking at that device, and --
16:44:38 8 and I don't recall the specific characteristics,
16:44:41 9 but -- but I do remember researching those alternative
16:44:45 10 designs by pulling up the websites and looking at
16:44:48 11 them.

16:44:48 12 Q. Okay.

16:44:49 13 A. So I -- I did research, you know, to support
16:44:52 14 what I was saying.

16:45:10 15 Q. That's not on the materials listed; right?

16:45:13 16 A. Oh, I don't know. It's in my report.

16:45:16 17 Q. Regarding the website for the Mistral-Air?

16:45:19 18 A. Yeah. I mean --

16:45:20 19 Let me turn to it.

16:45:21 20 Q. Okay.

16:45:22 21 A. Well I would think so. I recall doing it.
16:45:27 22 If you want me to take time to find that --

16:45:30 23 Q. You know what? Why don't we do it when we
16:45:32 24 go off the record next, and you can let me know if
16:45:34 25 it's there and we'll try to figure out --

1 A. Okay.

16:45:36 2 Q. -- if that's something to check.

16:45:39 3 Mistral-Air, with regard to new hazards,

16:45:42 4 what new hazards does Mistral-Air pose?

16:45:45 5 A. Well insomuch as it has different operating

16:45:49 6 characteristics, different design characteristics, so

16:45:53 7 those would pose particular hazards. As I -- as I

16:45:55 8 recall looking at the design and its operating

16:45:59 9 characteristics, since it was different from the Bair

16:46:02 10 devices in certain regards, those differences would --

16:46:07 11 would elicit potentially new hazards. So I -- I just

16:46:10 12 don't recall the specifics and I didn't document

16:46:13 13 those.

16:46:13 14 Q. The -- the Mistral-Air is a device that's

16:46:16 15 been held to be substantially equivalent to Bair

16:46:18 16 Hugger; correct?

16:46:19 17 A. Yes.

16:46:19 18 Q. That means that the -- the FDA determined

16:46:21 19 that the technological differences in the device did

16:46:24 20 not raise new questions of safety and effectiveness;

16:46:26 21 correct?

16:46:26 22 A. No, that's -- that's a misunderstanding of

16:46:28 23 that provision.

16:46:29 24 Q. Okay.

16:46:29 25 A. I'm surprised, I guess, we haven't touched

16:46:31 1 upon that before, the different technological
16:46:34 2 characteristics, whether they raise new types of
16:46:37 3 safety and effectiveness issues. So new types of
16:46:41 4 safety and effectiveness issues would be: Would I
16:46:44 5 analyze this -- this heating device in a different
16:46:47 6 manner than I would this other device? What would I
16:46:49 7 look at from an engineering point of view, from an
16:46:53 8 electrical safety point of view different from any
16:46:56 9 other heating device, from any water cooling/heating
16:46:59 10 device? And -- and the fact of the matter is there --
16:47:02 11 there's no fundamental differences in the assessment,
16:47:06 12 so there's no new types of issues to be -- to be
16:47:08 13 asked.

16:47:08 14 Q. With regard to the Mistral-Air, can you give
16:47:10 15 me an opinion within a degree of reasonable scientific
16:47:12 16 certainty regarding any new, enhanced hazards posed by
16:47:17 17 the device?

16:47:18 18 A. Enhanced hazards?

16:47:19 19 Q. Sure. Things in ways that it's more
16:47:22 20 hazardous than the Bair Hugger.

16:47:23 21 A. Well I'm not saying it's more hazardous, I'm
16:47:28 22 saying there may be new hazards.

16:47:29 23 Q. All right. Then let's talk about that. Can
16:47:30 24 you give me an opinion within a reasonable degree of
16:47:33 25 scientific certainty regarding the existence of new

16:47:38 1 hazards in the Mistral-Air device?

16:47:39 2 A. Well again, I'd have to again go through the
16:47:42 3 exercise of pulling up the device and looking at its
16:47:45 4 characteristics compared to the Bair Hugger. I did
16:47:46 5 identify some differences in technology which would
16:47:50 6 be -- raise potentially new risks which would have to
16:47:53 7 be assessed.

16:47:54 8 Q. Can -- can you give me an example of one?
16:47:56 9 Like what could be changed in the Mistral that makes a
16:47:59 10 new hazard?

16:48:01 11 A. New or different hazards? It could be the
16:48:04 12 power consumption, electrical characteristics. The --
16:48:11 13 the operating characteristics of the device itself may
16:48:14 14 have an impact upon the application of heat, so the
16:48:19 15 functional characteristics. So it's -- it's a matter
16:48:22 16 of -- of not just design but function, and if it's --
16:48:26 17 and where it's different, those may present
16:48:30 18 modifications of hazards.

16:48:31 19 Q. Okay. Those are reasons that --
16:48:34 20 Those are ways that it could present new
16:48:34 21 hazards.

16:48:35 22 A. Sure.

16:48:36 23 Q. Do you know any ways it does?

16:48:37 24 A. Well that would require further analysis.

16:48:38 25 Q. And that's not analysis you've done.

16:48:41 1 A. No.

16:48:41 2 Q. Okay.

16:48:41 3 A. No.

16:48:41 4 Q. For instance, you're not a biomedical
16:48:43 5 engineer; are you?

16:48:44 6 A. No. No. My -- my master's degree is in
16:48:47 7 physiology with an emphasis in biomedical
16:48:51 8 engineering, --

16:48:51 9 Q. Okay.

16:48:51 10 A. -- but it's not an engineering degree.

16:48:53 11 Q. Now Dr. David, who is a biomedical
16:48:55 12 engineer, gave an opinion that for each of these
16:48:57 13 devices, they are most likely safer and as effective
16:49:00 14 as the Bair Hugger. You aren't going to be giving
16:49:03 15 opinions to the contrary based on reasonable
16:49:06 16 engineering certainty; are you?

16:49:08 17 A. No. But he provides no foundation for his
16:49:11 18 statement.

16:49:11 19 Q. I understand you have criticisms. I'm not
16:49:15 20 asking you that. What I'm asking is a very simple
16:49:18 21 question, is if you can give me an opinion to a degree
16:49:19 22 of medical or scientific certainty that these devices
16:49:22 23 are not safer and as effective than the Bair Hugger.

16:49:28 24 A. I have -- don't have that in my report.

16:49:30 25 Q. Okay. You -- you understand what the

16:49:39 1 Tablegard system is.

16:49:40 2 A. Yeah. That's one of those devices.

16:49:42 3 Q. That's another one that's been held

16:49:44 4 substantially equivalent to the Bair Hugger.

16:49:45 5 A. Correct.

16:49:46 6 Q. Okay. That's a device that uses a -- an air

16:49:48 7 blower like the Bair Hugger.

16:49:51 8 A. I'll have to research it again. I don't

16:49:53 9 recall the specifics of it.

16:49:55 10 Q. Well let's -- let's just take a look at it

16:49:57 11 in Dr. David's report. Do you have that in front of

16:50:00 12 you?

16:50:00 13 A. Let's see.

16:50:01 14 Q. If not, I can give you a copy.

16:50:03 15 A. No. I probably have it.

16:50:05 16 Q. Here you go.

16:50:06 17 A. Okay.

16:50:12 18 Q. All right. You see that little product

16:50:14 19 right there?

16:50:15 20 A. Right. Right.

16:50:15 21 Q. Okay. Does that refresh your memory as to

16:50:19 22 what the Tablegard is?

16:50:20 23 A. Right.

16:50:22 24 Q. Okay. That product has an air blower in it;

16:50:24 25 right?

16:50:24 1 A. As far as I recall.

16:50:25 2 Q. It warms the air. Correct?

16:50:30 3 A. Yes.

16:50:31 4 Q. Distributes that air to the area of the
16:50:34 5 patient on the operating table.

16:50:35 6 A. Right.

16:50:35 7 Q. It does so with the intent to combat
16:50:38 8 operative hypothermia; correct?

16:50:41 9 A. Okay.

16:50:42 10 Q. You agree with that.

16:50:43 11 A. Yeah. It's substantially equivalent, so
16:50:46 12 yes.

16:50:46 13 Q. Yeah. That device uses, instead of an air-
16:50:51 14 circulation system, that is a closed-air system.

16:50:54 15 A. It's recirculating.

16:50:55 16 Q. Right.

16:50:56 17 A. Right.

16:50:56 18 Q. And you will agree with me you have seen in
16:51:00 19 Dr. David's report 3M has actually investigated how to
16:51:03 20 make the Bair Hugger a closed/recirculating system.

16:51:08 21 A. One of the ideations are you referring to?

16:51:14 22 Q. A couple of things, but sure.

16:51:14 23 Are you familiar with what Project Chameleon
16:51:17 24 is?

16:51:17 25 A. Chameleon. You know, that doesn't ring a

16:51:20 1 bell --

16:51:20 2 Q. Okay.

16:51:21 3 A. -- offhand.

16:51:21 4 Q. Okay.

16:51:22 5 MS. EATON: And let me just go back and

16:51:24 6 object to two questions ago.

16:51:25 7 MR. BANKSTON: To two questions ago.

16:51:26 8 MS. EATON: When you were characterizing Dr.
16:51:29 9 David's report.

16:51:31 10 MR. BANKSTON: I don't even know what I
16:51:31 11 said.

16:51:31 12 MS. EATON: I'm just objecting to the form.

16:51:34 13 MR. BANKSTON: Okay.

16:51:35 14 BY MR. BANKSTON:

16:52:05 15 Q. I want to talk to you a little bit about how
16:52:07 16 your report is organized, and so I think a -- a good
16:52:09 17 place to -- to go off on these questions is to look at
16:52:12 18 your report in the table of contents. I'm going to be
16:52:17 19 asking you some questions about your headings.

16:52:17 20 A. Sure.

16:52:20 21 Q. And you have a -- a background section, a
16:52:24 22 qualifications/credentials-type section, those sorts
16:52:28 23 of introductions into the report; right?

16:52:31 24 A. Yes.

16:52:31 25 Q. Okay. And I'm --

16:52:32 1 After that we get to a section that's
16:52:34 2 labeled Roman numeral Section VII, and that's the
16:52:36 3 methodology and opinions; correct?

16:52:38 4 A. Correct.

16:52:39 5 Q. This is the section of your report where
16:52:41 6 your opinions are summarized.

16:52:42 7 A. Yes.

16:52:42 8 Q. All of your opinions in this case, the
16:52:44 9 opinions you're offering affirmatively in this case,
16:52:47 10 are summarized within this one-to-13 list; correct?

16:52:50 11 A. That -- that's my core opinions, followed by
16:52:55 12 an additional rebuttal of Dr. David, yes.

16:52:57 13 Q. Correct. On -- and that's my next question.
16:53:00 14 On -- on VIII it is titled "SUMMARY REBUTTAL OF ALL
16:53:03 15 OF" -- excuse me -- "SUMMARY REBUTTAL OF DR. DAVID'S
16:53:06 16 LEGAL CONCLUSIONS AND RESPONSE TO PLAINTIFFS APRIL '17
16:53:11 17 CONCLUSIONS."

16:53:12 18 The April '17 conclusions, do you know what
16:53:15 19 that refers to?

16:53:18 20 MS. EATON: Do you mean April 2017?

16:53:18 21 MR. BANKSTON: Yeah, yeah, that's what I
16:53:19 22 mean.

16:53:20 23 A. I think -- I think that was the plaintiffs'
16:53:23 24 summation of their position on the aspects of their
16:53:29 25 case. It was a seven- or eight- or nine-point --

16:53:33 1 Q. That would be the punitive damage motion
16:53:35 2 we've been looking at today?

16:53:36 3 A. Right. Right.

16:53:37 4 Q. Okay.

16:53:37 5 A. Right.

16:53:38 6 Q. All right. So --

16:53:39 7 And I want to go through these 13 opinion
16:53:41 8 areas, okay, and ask you some questions about them.

16:53:44 9 A. Sure.

16:53:44 10 Q. Okay. So the first one is, "It is my
16:53:48 11 opinion that safety and effectiveness factored into
16:53:50 12 FDA's review of every Bair Hugger 510(k);" correct?

16:53:53 13 A. Correct.

16:53:54 14 Q. Okay. And continuing on with 510(k)
16:53:57 15 opinions, your second opinion is, "It is my opinion
16:54:00 16 that the Traditional 510(k)s for the Bair Hugger
16:54:04 17 Models 505 and 750 met all FDA premarket requirements,
16:54:09 18 recommendations of guidance, and industry standards.
16:54:12 19 FDA orders clearing these devices were -- provided, in
16:54:15 20 part, reasonable assurance that the Bair Huggers were
16:54:18 21 safe and effective;" correct?

16:54:19 22 A. Correct.

16:54:21 23 Q. All right. Now these are legal conclusions;
16:54:22 24 correct?

16:54:22 25 MS. EATON: Object to the form of that

16:54:24 1 question.

16:54:24 2 A. Well these are regulatory opinions.

16:54:25 3 Q. That's law; right?

16:54:26 4 A. Huh?

16:54:27 5 Q. Regulations are laws passed by the

16:54:30 6 government.

16:54:30 7 A. No. Regulations are -- implement the laws
16:54:33 8 passed by the government.

16:54:33 9 Q. Okay. It's --

16:54:35 10 Part of the legal structure of our country
16:54:36 11 is we have a regulatory regime.

16:54:38 12 A. Yes.

16:54:38 13 Q. Okay.

16:54:39 14 A. And so I administer my duties at FDA on --
16:54:43 15 according to the regulations.

16:54:45 16 Q. Okay. And you have also given the opinion
16:54:47 17 in -- in these two subheadings that the 510(k) process
16:54:51 18 itself evaluates and makes judgment calls on safety
16:54:56 19 and effectiveness; correct?

16:54:57 20 A. My opinion is clear, that safety and
16:55:01 21 effectiveness factors into 510(k) reviews.

16:55:03 22 Q. Okay.

16:55:03 23 A. And I explain that.

16:55:04 24 Q. Now that's the -- that's the opinion about
16:55:07 25 the effect of the regulations that has been prohibited

16:55:10 1 on several occasions.

16:55:11 2 A. No.

16:55:12 3 Q. You don't think so.

16:55:14 4 A. I don't think so.

16:55:14 5 Q. Okay. So after having dealt -- went through
16:55:19 6 that experience of having opinions limited in cases,
16:55:20 7 you don't believe that these are the same kind of
16:55:22 8 opinions.

16:55:23 9 A. They are not.

16:55:23 10 Q. Okay. How are your opinions --

16:55:29 11 For instance, in this case regarding 510(k),
16:55:32 12 can you tell me how they're different than, say, what
16:55:35 13 was offered in Ethicon?

16:55:43 14 A. Probably by not, in Ethicon, acknowledging
16:55:48 15 more proactively and affirmatively the difference in
16:55:52 16 the statutory and regulatory standards between
16:55:57 17 premarket approval and -- and 510(k)s, which -- which
16:56:01 18 I certainly recognize and support and believe is
16:56:05 19 entirely the case. But -- but in these opinions, as
16:56:11 20 we've discussed when we talk about intended use, when
16:56:14 21 we talk about technology, do not the words safety and
16:56:19 22 effectiveness enter into that conversation? Of course
16:56:20 23 they do. And I'd further support the contention with
16:56:24 24 reference to FDA's statements that -- in guidance
16:56:29 25 documents that safety and effectiveness factors into

16:56:31 1 510(k) reviews.

16:56:32 2 Q. Now I don't think we have any dispute or
16:56:34 3 quarrel between the two of us that the words safety
16:56:36 4 and effectiveness appear in 510(k) documents and are
16:56:39 5 part of 510(k) flowcharts and decision-making; right?

16:56:41 6 A. Well I hope not.

16:56:42 7 Q. Yeah. I wouldn't think so. We do --

16:56:45 8 We have had a difference today about whether
16:56:47 9 the 510(k) regime is effective at all at doing that;
10 right?

16:56:53 11 A. Well you've asked a couple questions that --
16:56:56 12 that allude to -- to FDA's ability to conduct its --
16:57:04 13 its evaluation process, if that's what you're asking.

16:57:06 14 Q. And then the FDA's actual study of the
16:57:09 15 510(k) process, which was published just as you left
16:57:13 16 the agency, that also tends to find -- have some
16:57:16 17 serious criticisms of the effectiveness of the 510(k)
16:57:18 18 process in safeguarding American patients; correct?

16:57:24 19 A. Yes, I -- I --

16:57:26 20 The IOM opinions are what they are, but my
16:57:28 21 position is you have to evaluate these devices. We're
16:57:33 22 talking about Bair Huggers today. Do their broad,
16:57:37 23 overarching opinions apply to the Bair Hugger? And my
16:57:41 24 opinion is they do not.

16:57:42 25 Q. Your number three opinion is that "It is my

16:57:45 1 opinion that after clearance of the Bair Hugger" --

16:57:49 2 excuse me.

16:57:49 3 "It is my opinion that after the clearance

16:57:50 4 of the Model 750 FDA reconfirmed the safety and

16:57:54 5 effectiveness of the Bair Hugger forced air technology

16:57:57 6 by clearing additional 510(k)s for additional uses and

16:58:00 7 new promotional claims;" correct?

16:58:02 8 A. Right.

16:58:03 9 Q. That's your opinion?

16:58:04 10 A. But my point is every time FDA reviews a new

16:58:07 11 510(k), it has a renewed chance to evaluate the

16:58:10 12 technology.

16:58:11 13 Q. My -- my question here is this is another

16:58:14 14 opinion dealing with the 510(k) process and the safety

16:58:17 15 ramifications of it; correct?

16:58:19 16 A. Right. That safety and effectiveness

16:58:22 17 factors into those 510(k) reviews, also relying upon

16:58:25 18 the history of the product to that point in time.

16:58:27 19 Q. Your number four opinion is, "It is my

16:58:30 20 opinion that FDA cleared the Model 750 with full

16:58:33 21 knowledge that the air filter to be used in the Model

16:58:36 22 750 was not a HEPA filter;" correct?

16:58:38 23 A. Correct.

16:58:39 24 Q. Did any of plaintiffs' experts say that FDA

16:58:41 25 thought there was a HEPA filter?

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16:58:45 1 A. Well this is an opinion. I expand upon it.

16:58:53 2 And that's not the entire opinion, but --

16:58:58 3 Q. Okay. And if the FDA -- excuse me. If

16:59:02 4 Arizant sent the FDA -- no. Let's back up and do that
16:59:07 5 again.

16:59:07 6 If 3M sent the FDA a letter in December of
16:59:12 7 2016 meaning to correct information to tell the FDA
16:59:15 8 there was not a HEPA filter as the FDA had previously
16:59:18 9 reported, would you agree with me that sort of
16:59:21 10 conflicts with the idea that the FDA had full
16:59:24 11 knowledge that there wasn't a HEPA filter in the
16:59:26 12 device?

16:59:27 13 MS. EATON: Object to the form of the
16:59:28 14 question.

16:59:30 15 A. Yeah. I -- I -- I don't think there was a
16:59:33 16 degree of impact of that misstatement in the re --
16:59:38 17 EIR, so --

16:59:38 18 Q. Well I don't --

16:59:39 19 I'm not concerned about its impact. What I
16:59:43 20 want to know is if the FDA is stating in its official
16:59:45 21 publications that the Bair Hugger has a HEPA filter,
16:59:47 22 doesn't that kind of contradict the opinion that they
16:59:50 23 had full knowledge it doesn't have a HEPA filter?

16:59:52 24 MS. EATON: Object to the form of the
16:59:53 25 question.

16:59:54 1 A. I stand by my opinion. When they cleared
16:59:56 2 the 750, it was clear they knew it wasn't going to be
16:59:59 3 a HEPA filter, they knew it was going to have the .2
17:00:01 4 micron characteristics of the prior filters.

17:00:05 5 Q. Now the other part of that opinion of four
17:00:08 6 that continues over is, "There is no FDA regulatory
17:00:12 7 requirement for a warming device to meet a specific
17:00:16 8 air filter standard."

17:00:16 9 A. That's correct. Nor is there any other
17:00:18 10 industry standard for that matter.

17:00:20 11 Q. Okay. And you have told me that you're not
17:00:26 12 in any way knowledgeable about what air filters are
17:00:29 13 required or what air filters are standard inside of
17:00:33 14 orthopedic operating rooms; correct?

17:00:35 15 A. Well I'd have to evaluate -- re-evaluate
17:00:42 16 what I -- what I did for -- to examine HEPA filters
17:00:46 17 and the classifications and other data on hospital use
17:00:51 18 of filters, so -- and -- and that --

17:00:55 19 It's in fact evolving, even as deposition
17:00:59 20 testimony is provided, that standards committees are
17:01:01 21 reassessing what their requirements should be.

17:01:04 22 Q. So I'm still confused. Do you know or do
17:01:07 23 you not know or have any information?

17:01:08 24 A. Well I think I may have known, I just -- I
17:01:11 25 just don't recall.

17:01:11 1 Q. Okay.

17:01:12 2 A. Because I did investigate filtration
17:01:15 3 standards and classifications and -- and usage because
17:01:20 4 there -- there are standards related to that, and
17:01:23 5 usage conditions.

17:01:24 6 Q. All right. But that's not something you've
17:01:27 7 relied on for your report today.

17:01:28 8 A. Well I did to a degree, because I recall
17:01:34 9 looking at the industry standard for MERV and
17:01:40 10 application of MERV, so -- so yes, I did look at these
17:01:44 11 things and refer to them in my report.

17:01:45 12 Q. Right. Well --

17:01:45 13 And I understand that you were citing a -- a
17:01:48 14 MERV specification for general surgeries. What I --
17:01:52 15 what I'm trying to understand is I believe we had
17:01:55 16 discussed earlier you were not familiar with any
17:01:58 17 standards for filtration in an ultraclean orthopedic
17:02:00 18 procedure.

17:02:01 19 A. No. I don't --

17:02:03 20 MS. EATON: Object to the form of that
17:02:03 21 question.

17:02:03 22 A. No. I don't know which -- what exists,
17:02:06 23 what's generally applied by industry in -- in
17:02:09 24 healthcare facilities.

17:02:10 25 Q. Okay. Your next opinion, number five, is

17:02:13 1 it's your opinion that design history files for the
17:02:17 2 Bair Hugger models 505 and 750 provide reasonable
17:02:19 3 assurance of safety and effectiveness of the designs
17:02:23 4 of these devices; correct?

17:02:23 5 A. Correct.

17:02:23 6 Q. Okay. We've talked a little bit about that;
17:02:26 7 correct?

17:02:26 8 A. Yes.

17:02:26 9 Q. Okay. Number six is, "It is my opinion
17:02:29 10 there was no unacceptable risk or regulatory
17:02:32 11 imperative prompting Arizant to modify the Model 750
17:02:36 12 to include a filter at the distal end of the air
17:02:39 13 supply hose or a silver coating to the interior of the
17:02:43 14 hose." Did I read that correct?

17:02:45 15 A. Correct.

17:02:45 16 Q. Okay. So when we say that there was no
17:02:49 17 regulatory imperative, nothing in the law required
17:02:52 18 them to have an alternative design; right?

17:02:54 19 A. Right. There was no recall or documented
17:02:59 20 patient harm that -- that would drive this
17:03:03 21 manufacturer to make a design change.

17:03:04 22 Q. Okay. But in terms of the risk that may
17:03:07 23 have imposed, that's not something medically you can
17:03:09 24 speak about; right?

17:03:12 25 A. I would speak to MDR reports, literature

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17:03:16 1 reports that would be -- be brought to bear, but not
17:03:18 2 as a clinical clinician assessing those data.

3 Q. Okay.

17:03:23 4 A. If you understand what I'm saying.

17:03:25 5 Q. Right. And that's not an engineering
17:03:26 6 opinion either; correct?

17:03:27 7 A. It's not an engineering opinion, no.

17:03:30 8 Q. Okay. And number seven, "It is my opinion
17:03:32 9 that the MedWatch reports to FDA in 2016 from Dr.

17:03:37 10 Augustine and his company, all of which were third

17:03:40 11 hand voluntary reports based on Dr. Augustine aided

17:03:44 12 litigation, are biased, incomplete, and unverified.

17:03:48 13 3M had a -- has a reasonable regulatory basis for not
17:03:53 14 reporting litigation-based events to the FDA

17:03:56 15 concerning allegations of infections associated with a
17:03:59 16 Air -- with a Bair Hugger." Correct?

17:04:02 17 A. Correct.

17:04:02 18 Q. Okay. When it comes to reporting litigation
17:04:07 19 events to the FDA concerning allegations of

17:04:11 20 infections, nobody on the plaintiffs' side is talking
17:04:13 21 about that, right, that you're responding to?

17:04:17 22 A. Oh, we -- we kind of went through this. If
17:04:20 23 you want to cover the same ground --

17:04:23 24 Q. Just a little bit.

17:04:29 25 This isn't rebuttal to anybody is what I'm

17:04:31 1 saying.

17:04:31 2 A. No. Well --

17:04:34 3 MS. EATON: Object to the form of the
17:04:34 4 question.

17:04:34 5 A. You know, I think as I answered, there is
17:04:36 6 enough in the complaint and -- and even Dr. David's
17:04:42 7 report that opens the door to the need -- and
17:04:48 8 deposition testimony and questions that you on
17:04:50 9 plaintiffs' side have asked, for me to -- to have
17:04:54 10 found it necessary to explore that.

17:04:56 11 Q. Okay. And -- and one of those things that
17:05:00 12 this does, though, directly address is plaintiffs'
17:05:03 13 complaint. You --

17:05:04 14 This is meant to rebut or address the
17:05:08 15 allegations made in plaintiffs' complaint.

17:05:10 16 A. The regulatory aspects, yes.

17:05:12 17 Q. Okay. Number eight is, "It is my opinion
17:05:16 18 that the labeling for the Bair Hugger Models 505 and
17:05:19 19 750 met regulatory requirements and are consistent
17:05:21 20 with industry standards." And that "There is no basis
17:05:23 21 to find the labeling misbranded." Do you remember
17:05:25 22 that?

17:05:26 23 A. Correct.

17:05:26 24 Q. Okay. That's one we talked pretty
17:05:29 25 extensively about; right?

17:05:31 1 A. Yes.

17:05:31 2 Q. Do you remember our discussions on that?

17:05:32 3 A. Yes.

17:05:32 4 Q. Okay. Are you going to have any opinions
17:05:42 5 about the warning in labeling of the model 200?

17:05:45 6 Because I don't see that in the report.

17:05:48 7 A. No, I didn't address that.

17:05:48 8 Q. Okay. Number nine opinion, "It is my
17:05:57 9 opinion that a 2010 Warning Letter from FDA to

17:06:01 10 Arizant, Incorporated did not result in any

17:06:05 11 observation regarding MDRs for complaints of infection

17:06:08 12 and the findings in the letter which were quickly

17:06:11 13 resolved does not undermine the reasonable assurance

17:06:13 14 of safety and effectiveness of the Bair Hugger."

17:06:16 15 That's your opinion?

17:06:17 16 A. Yes, it is.

17:06:18 17 Q. Okay. Now that's also another one that is
17:06:20 18 addressed to the extent it's responding to something
17:06:23 19 in the plaintiffs' complaint; correct?

17:06:26 20 A. Right. I think Dr. David talks about that
17:06:31 21 inspection again.

17:06:31 22 Q. Well we'll --

17:06:32 23 Actually, when we're done here, I'm going to
17:06:34 24 have you look for that in terms of is there any
17:06:36 25 discussion of the warning letter from Dr. David.

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17:06:39 1 A. Well as I said, it's part and parcel. I --

17:06:42 2 I find it difficult to separate --

17:06:46 3 Q. The inspection -- -

17:06:47 4 A. -- the inspection and observations from the
17:06:50 5 ultimate disposition by FDA.

17:06:51 6 Q. It's difficult for you to separate the
17:06:53 7 infections from the burns. They're all part of the
17:06:56 8 same thing.

17:06:57 9 MS. EATON: Object to the form of the
17:06:58 10 question.

17:06:58 11 A. That's not what I said.

17:07:01 12 Q. Okay. I'm asking you if that's true.

17:07:04 13 A. Well I looked at the purpose of the
17:07:07 14 inspection and what was found and what FDA ultimately
17:07:10 15 thought about. Because the 483 is not conclusions of
17:07:14 16 FDA; you have to look at the warning letter to see the
17:07:17 17 conclusions of it.

17:07:18 18 Q. Okay. So when looking at the warning
17:07:20 19 letter, there is information in it that relates to
17:07:23 20 infections; correct?

17:07:24 21 A. In the --

17:07:26 22 No, there's no --

17:07:27 23 Q. There's --

17:07:28 24 You don't believe in the warning letter that
17:07:30 25 there's any information suggesting that there was an

17:07:32 1 inspection of Arizant's facility for infection

17:07:36 2 concerns.

17:07:36 3 A. Well it would have been relevant because

17:07:39 4 they would be looking at MDR reporting generally.

17:07:41 5 Q. Okay. Well let's look at --

17:07:43 6 Then so you'll agree with me the -- the

17:07:45 7 warning letter that you're discussing, the 2010

17:07:48 8 warning letter, has nothing to do with infection.

17:07:50 9 A. I don't think that was the focus of it.

17:07:52 10 Q. Right. No, I'm -- I'm totally agreeing with

17:07:55 11 you there.

17:07:55 12 A. Right.

17:07:55 13 Q. That has nothing to do with --

17:07:56 14 A. 2016 it was certainly relevant.

17:07:58 15 Q. Sure, sure.

17:08:01 16 So when Dr. David is talking about the

17:08:01 17 inspection establishment report -- rather,

18 establishment inspection report --

19 Is that how you say it?

20 A. Establishment inspection report.

17:08:02 21 Q. When he's talking about that, he's talking

22 about the inspection of the facility for infection

17:08:15 23 issues; correct?

17:08:15 24 A. No. I -- he --

17:08:16 25 You know, I might be incorrect here, but he

17:08:19 1 addressed -- he refers to the 2009 inspection.

17:08:22 2 Q. Right. And yeah, I think we're on the same
17:08:23 3 page.

17:08:24 4 A. So, you know, the inspection is what it is
17:08:27 5 and what was found and what FDA responded to, so since
17:08:31 6 he addressed it in -- in -- in negative terms, I
17:08:36 7 believe, you know, I felt it necessary to put the
17:08:41 8 proper regulatory perspective on that.

17:09:13 9 Q. Your next opinion is number 10, "It is my
17:09:16 10 opinion that in a 2012 Warning Letter to Augustine
17:09:22 11 Biomedical & Design, LLC the FDA repudiated claims
17:09:27 12 against the Bair Hugger made by Augustine Biomedical &
17:09:31 13 Design, LLC;" correct?

17:09:32 14 A. Correct.

17:09:33 15 Q. Okay. Now again, this is one of those
17:09:35 16 things that is directed at the plaintiffs' complaint,
17:09:37 17 if anything, not a plaintiffs' expert report; correct?

17:09:40 18 MS. EATON: Object to the form of the
17:09:41 19 question.

17:09:41 20 A. Well I'll have to look at the --

17:09:43 21 Because I usually preface with some --

17:09:46 22 Q. Sure. Yeah. If you want to flip to page
17:09:48 23 77.

17:09:48 24 A. I will.

17:09:49 25 Q. And if you can tell me, does any plaintiffs'

17:09:51 1 expert discuss the 2012 warning letter?

17:10:01 2 A. Perhaps not, but I found it relevant because

17:10:04 3 it's all part and parcel of the same issue of Dr.

17:10:12 4 Augustine's claims against the Bair Hugger.

17:10:13 5 Q. Correct. And -- and I think what we may be

17:10:15 6 able to agree on is that while maybe not relevant

17:10:18 7 directly to a specific expert report, it is in your

17:10:23 8 opinion relevant to the general subject matter of the

17:10:25 9 case.

17:10:25 10 A. Correct.

17:10:27 11 Q. Okay. Thank you.

17:10:27 12 A. Correct.

17:10:28 13 Q. Number 11 is, "It is my opinion that

17:10:33 14 CDC/HICPAC and FDA meeting discussions concerning a

17:10:39 15 heater-cooler device are unrelated to forced air

17:10:43 16 warming devices;" correct?

17:10:44 17 A. Correct.

17:10:44 18 Q. We haven't gotten to talk much about the

17:10:47 19 heater/cooler today; have we?

17:10:48 20 A. No.

17:10:49 21 Q. I don't think it's come up really.

17:10:50 22 A. No.

17:10:50 23 Q. Let's talk about that for a minute right

17:10:53 24 now. You understand that there are --

17:10:55 25 This is the part that I think you would

17:10:57 1 agree that is addressed not just to Dr. David but

17:11:00 2 at -- at Dr. William Jarvis as well.

17:11:02 3 A. Right. He speaks to it.

17:11:04 4 Q. Okay. And in Dr. Jarvis's professional

17:11:07 5 clinical opinion, there are -- there is relevance to

17:11:11 6 the heater/cooler unit. That's what he believes;

17:11:15 7 correct?

17:11:16 8 A. He has a different opinion.

17:11:18 9 Q. Right. And that's what his opinion is, and

17:11:20 10 that's the opinion you're going to address, is his

17:11:24 11 opinion that those are relevant to the Bair Hugger;

17:11:26 12 correct?

17:11:26 13 A. Right. And -- and Dr. David talks -- speaks

17:11:29 14 to it as well.

17:11:30 15 Q. Yeah. And I don't necessarily think --

17:11:33 16 He maybe talks to the heater/coolers, so

17:11:36 17 let's talk to the other part of HICPAC, which is the

17:11:38 18 part Dr. David talks about. Because he doesn't really

17:11:41 19 get into the specifics of heater/cooler, but he does

17:11:43 20 talk about something from that report. And do you

21 remember a phrase at the FD -- the HICPAC draft minute

17:11:48 22 pad that said, "Nothing that blows air should be in an

17:11:49 23 OR, if possible?"

17:11:50 24 A. Right. And I think too much is made of that

17:11:53 25 in the HICPAC comments by Dr. David and Dr. Jar -- Dr.

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17:11:59 1 Jarvis, and I explained my reasoning in my report.

17:12:01 2 Q. Sure, sure, absolutely. And -- and you
17:12:03 3 wouldn't agree with that statement then, "Nothing that
17:12:05 4 blows air should be in the OR, if possible."

17:12:09 5 A. I -- I wouldn't take action based upon that
17:12:13 6 statement were I still at FDA. It's -- it's a -- it's
17:12:17 7 a passing comment by somebody in an unsubstantiated or
17:12:22 8 undefined purpose or meaning, and -- and it's almost
17:12:27 9 an absurd comment because of course there's lots of
17:12:30 10 things blowing air in an OR, so what are you going to
17:12:33 11 do?

17:12:33 12 Q. Well certain things have to be in an OR;
17:12:37 13 right?

17:12:37 14 A. Right.

17:12:37 15 Q. Yeah. Not -- not a Bair Hugger though;
17:12:38 16 right? You have alternative designs that don't blow
17:12:41 17 air; right?

17:12:42 18 A. No. No. I think the statement --
17:12:44 19 My point is it's -- whoever made it, and
17:12:46 20 there's no attribution actually I don't think, and
17:12:49 21 it's certainly not addressed by HICPAC, --

17:12:51 22 Q. My question --

17:12:52 23 A. -- it's made in a statement -- let me
17:12:55 24 finish -- statement made by someone in passing,
17:12:57 25 certainly not actionable by anybody, so -- so are you

17:13:02 1 going to change the world because some -- some unknown
17:13:06 2 person made an unsubstantiated statement in one
17:13:09 3 meeting regarding a wholly different device? So, you
17:13:13 4 know, it's just -- it's just too awkward.

17:13:17 5 Q. My question is: There are devices that
17:13:22 6 fulfill the same role as the Bair Hugger that do not
17:13:25 7 blow air into the operating room.

17:13:29 8 A. Well I'll say that do not function in the
17:13:31 9 same manner as the Bair Hugger.

17:13:33 10 Q. Okay. There are other devices that have air
17:13:38 11 blowers that warm air that deliver heat to the patient
17:13:42 12 and accomplish the same clinical goals as Bair Hugger
17:13:45 13 that do not blow air into the operating room. Do you
17:13:48 14 agree with that?

17:13:48 15 A. There's a --

17:13:49 16 As I said, there's products that have
17:13:51 17 different characteristics from the Bair Hugger, may or
17:13:54 18 may not be as effective. Who knows? But, you know,
17:13:58 19 that's -- that's where I'll leave it.

17:13:59 20 Q. In terms of whether they're effective or not
17:14:02 21 or safer or not than the Bair Hugger, certainly you
17:14:06 22 don't know.

17:14:06 23 A. No. I haven't assessed those devices --

17:14:08 24 Q. Okay.

17:14:08 25 A. -- to the degree necessary to take

17:14:11 1 conclusions. Nor has Dr. David.

17:14:13 2 MR. BANKSTON: I object to the

17:14:16 3 non-responsive part.

17:14:16 4 Q. Opinion number 12 is, "It is my opinion that

17:14:19 5 Arizant appropriately monitored the literature and

17:14:23 6 other sources of information regarding its products

17:14:24 7 and investigated concerns regarding its device in

17:14:28 8 accordance with FDA post market procedures and

17:14:30 9 industry practice. Arizant also conducted field

17:14:35 10 actions based upon postmarket information as

17:14:37 11 appropriate." Correct?

17:14:38 12 A. Yes.

17:14:38 13 Q. Okay. So the first part of this opinion I

17:14:40 14 want to make sure I understand is some of this is a

17:14:44 15 regulatory opinion, that they complied with what is

17:14:48 16 required under the FDA in terms of postmarket.

17:14:50 17 A. Yes. That's the purpose of my report.

17:14:53 18 Q. Okay. Now there's another part of this,

17:14:56 19 though, where you talk about field actions. Is -- is

17:15:00 20 a field action something that is part of -- of

17:15:05 21 fulfilling your regulatory obligations under the FDA,

17:15:07 22 or is that something separate?

17:15:08 23 A. No. That's all part and parcel of the

17:15:11 24 obligations of a manufacturer --

17:15:12 25 Q. Okay. So --

17:15:12 1 A. -- in a postmarket --

2 Q. So ev --

17:15:15 3 A. -- environment.

17:15:16 4 Q. Ev --

5 A. Excuse me.

6 Q. I'm sorry. I keep doing it.

17:15:16 7 Everything in opinion 12 concerns regulatory
17:15:22 8 concerns, your regulatory opinions, and about the
17:15:25 9 company's compliance with those regulations.

17:15:27 10 A. Yes.

17:15:27 11 Q. Okay. Now 13 is the additional rebuttal
17:15:33 12 opinions to Dr. David.

17:15:34 13 A. Right, where I -- where I walk through his
17:15:37 14 report page by page and identify areas I believe
17:15:45 15 require comment and rebuttal and that were not
17:15:48 16 contained previously in the other opinions.

17:15:50 17 Q. Okay. So that was at page 85 to 109 in
17:15:54 18 opinion 13.

17:15:54 19 A. Correct.

17:15:57 20 Q. And then we get to section VIII, Roman
17:15:57 21 numeral VIII, and that's also a rebuttal of Dr.
17:16:00 22 David's conclusions, in part; right?

17:16:02 23 A. Right. Because in sum, as he concluded his
17:16:06 24 report, or -- and partially embodied in the report, he
17:16:11 25 made -- he made regulatory conclusions regarding the

17:16:15 1 product, and -- and I wanted to put that -- that
17:16:19 2 process in proper perspective and to -- and to rebut
17:16:23 3 that in -- in a summation form.

17:16:26 4 Q. Okay. I want to talk to you real quickly
17:16:28 5 about some of your -- some of these additional
17:16:32 6 rebuttal opinions that you identify in 13.

17:16:33 7 A. Sure.

17:16:34 8 Q. And because it's not spelled out in the
17:16:38 9 table of contents.

17:16:38 10 A. Correct.

17:16:38 11 Q. I just wanted to ask you about a couple of
17:16:39 12 them.

17:16:39 13 A. Sure.

17:16:40 14 Q. First of all, is -- you understand he -- he
17:16:42 15 took a look at an eBay device --

16 A. Yes.

17:16:44 17 Q. -- that he bought?

17:16:44 18 A. Yes.

17:16:45 19 Q. And I think you say that it doesn't
17:16:49 20 represent a service device currently in use or you
17:16:52 21 don't even know it's within its specifications. It's
17:16:55 22 not -- you can't use it to prove anything. Is that
17:16:58 23 basically true?

17:16:59 24 A. Right. It's -- it's -- it's only --

17:17:01 25 I mean you can take at gross look at it, but

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17:17:04 1 it's -- you can't make -- render a conclusion based on
17:17:06 2 it.

17:17:06 3 He didn't describe his methodology, the
17:17:10 4 foundation for his statements in -- in many regards,
17:17:13 5 so --

17:17:14 6 Q. Well he -- he in fact says the same exact
17:17:16 7 thing; right? "The machine is not representative of a
17:17:19 8 typical device. Out of spec. I -- I can't use it
17:17:20 9 to -- to make it a representation of the actual
17:17:23 10 device."

17:17:23 11 A. Right, but yet he -- he entitles his report
17:17:27 12 a hazard analysis.

17:17:29 13 Q. Uh-huh.

17:17:29 14 A. Well, you know, that's -- it's a -- that's
17:17:31 15 a -- probably the most rudimentary explanation in a
17:17:36 16 hazard -- so-called hazard analysis I've ever seen, so
17:17:41 17 he -- he could probably do without it, to tell you the
17:17:43 18 truth.

17:17:44 19 Q. Yeah. He didn't need --

17:17:45 20 A. Because it has no merit.

17:17:46 21 Q. Right. He didn't need to look at a device.

17:17:48 22 A. Right.

17:17:50 23 Q. The only purpose for him looking at the
17:17:51 24 device is so he could see what it looks like when you
17:17:53 25 turn it on, where the air goes. He's not really using

17:17:58 1 it for anything; right?

17:17:58 2 A. Well I'm not --

17:17:58 3 MS. EATON: Object to the form of the
17:17:59 4 question.

17:17:59 5 A. I'm not sure that's the case. I mean he
17:18:01 6 looked at that device and -- and -- and -- and gained
17:18:05 7 opinions -- impressions of the device based on that
17:18:06 8 examination, and then he approached the rest of his
17:18:10 9 analysis.

17:18:10 10 Q. Right. Like one opinion that he gave was
17:18:12 11 that he could tell, from the fact that this device was
17:18:15 12 a used device, he could look at the feet of the device
17:18:19 13 and tell it had been placed on the floor; right?

17:18:21 14 A. Fine.

17:18:21 15 Q. Is that -- is that okay with you? Are
17:18:21 16 you --

17:18:23 17 Is that an opinion you're not okay with or
17:18:26 18 are okay with?

17:18:26 19 MS. EATON: Object to the form of the
17:18:28 20 question.

17:18:28 21 A. Those sorts of observations are -- are
17:18:32 22 interesting. I -- it doesn't contribute to his hazard
17:18:36 23 analysis.

24 Q. Sure.

17:18:38 25 A. None -- none of that really contributed to

17:18:39 1 his hazard analysis.

17:18:40 2 Q. You were --

17:18:43 3 A. But containing it in a hazard analysis
17:18:46 4 attempts to give it some importance in regard to
17:18:50 5 that -- the focus of his review.

17:18:51 6 Q. You know where the device is used in the OR
17:18:54 7 has been somewhat of a point of contention in the
17:18:56 8 case.

17:18:56 9 A. Yes.

17:18:57 10 Q. Okay. So evidence that the device was used
17:18:59 11 in a certain place is relevant; right?

17:19:03 12 A. Not in his particular assessment.

17:19:05 13 Q. Well he had found that Bair Huggers that are
17:19:08 14 being used in the field, here's one that has wear on
17:19:12 15 the floor, It's definitely been used on the floor.
17:19:13 16 That's relevant; right?

17:19:15 17 MS. EATON: Object to the form of the
17:19:16 18 question.

17:19:17 19 A. Well that's an observation, but it's not
17:19:20 20 particularly useful in regard to hazard analysis.

17:19:22 21 Q. Okay. Now you've never touched the device,
17:19:25 22 unlike Dr. David; right?

17:19:28 23 A. No, I have not, --

17:19:28 24 Q. Okay.

17:19:28 25 A. -- because of the very same reasons I

17:19:29 1 describe as being problematic with Dr. David's
17:19:32 2 examination. So if -- if you -- if you touch the
17:19:35 3 device, if you are examining the device, what -- what
17:19:37 4 is that -- what is that helping you with? What is
17:19:39 5 that doing for you in regard to your analysis and your
17:19:42 6 report?

17:19:45 7 Q. That's a --

17:19:45 8 A. So --

17:19:45 9 Q. That's a -- a question a biomedical engineer
17:19:47 10 could maybe answer for us; correct?

17:19:49 11 A. Well I'm not without expertise in evaluating
17:19:52 12 devices, so I -- I think you have to be very careful
17:19:56 13 when requesting devices and conducting quasi-analyses
17:20:01 14 of devices for -- for dubious purposes.

17:20:04 15 Q. Here's -- I -- here's the thing is I --
17:20:08 16 I --

17:20:08 17 I know maybe we're up in the air about who
17:20:10 18 has what expertise, so I'm not trying to tie this to
17:20:13 19 any specific person, but you agree with me you're
17:20:16 20 going to defer to experts on filtration, computational
17:20:21 21 fluid dynamics, and HVAC, on those topics.

17:20:25 22 A. Yes.

17:20:25 23 MR. BANKSTON: Okay. Let's go off the
17:20:27 24 record for just a minute.

17:20:29 25 THE REPORTER: Off the record, please.

17:20:33 1 (Recess taken.)

17:28:18 2 BY MR. BANKSTON:

17:28:21 3 Q. Okay. On page 92, --

17:28:23 4 A. Yes.

17:28:23 5 Q. -- do you see the phrase that talks about

17:28:25 6 "None of the technological issues raise..." See if

17:28:29 7 you can find that phrase for me.

17:28:30 8 A. On page 92.

17:28:31 9 Q. Page 92, yes, sir. I hope I got that right.

17:28:34 10 A. Right. "None of the technological changes

17:28:37 11 raise new types of safety and effectiveness

17:28:40 12 questions..."

17:28:40 13 Q. And it continues to say "and standards-based

17:28:42 14 or state of the art test methodologies enabled

17:28:46 15 assessment of the changes;" correct?

17:28:47 16 A. Correct.

17:28:48 17 Q. What state-of-the-art test methodologies are

17:28:51 18 you referring to?

17:28:52 19 A. Those were electrical test standards, those

17:28:55 20 were flow standards that -- flow tests that they used,

17:29:02 21 so -- so -- so generally those are what I'm talking

17:29:05 22 about.

17:29:05 23 Q. None of those state-of-the-art test

17:29:07 24 methodologies you were discussing in that statement,

17:29:09 25 in that opinion, refer to tests for airborne

17:29:12 1 contamination issues; correct?

17:29:13 2 A. I -- I don't think there are or were a
17:29:18 3 state-of-the-art or standards-based test methodology.

17:29:24 4 Q. Okay.

17:29:25 5 A. A lot of people were winging it.

17:29:28 6 Q. I want to --

17:29:30 7 Last thing I want to quickly ask you about
17:29:33 8 is: Over the course of your time at the FDA --

17:29:40 9 The FDA has leadership above you; correct?

17:29:43 10 A. Has leadership above me?

17:29:46 11 Q. Correct. The FDA commissioner, for example.

17:29:48 12 A. Yes, there are -- there were persons in the
17:29:50 13 organizational chart above me, yes.

17:29:51 14 Q. FDA commissioner helps define the mission of
17:29:57 15 the -- of the organization and help it accomplish its
17:29:57 16 mission; correct?

17:29:57 17 A. Overall, yes.

17:29:58 18 Q. Okay. And affects the culture of the
17:30:00 19 organization.

17:30:01 20 A. May or may not. You'd be surprised how much
17:30:03 21 a new commissioner doesn't change the culture, but --
17:30:07 22 but it may have an effect.

17:30:08 23 Q. Well let's talk about that for a minute. I
17:30:10 24 would imagine the first commissioner that you had
17:30:12 25 pretty deep experience with, considering you began in

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17:30:15 1 2003, so you came in under a commissioner who was just
17:30:18 2 leaving; correct?

17:30:20 3 A. I came to FDA --

4 Q. Oh.

17:30:20 5 A. -- in 1976.

17:30:21 6 Q. I made a mistake. I meant in terms of when
17:30:23 7 you came to work as a director in the Office of
17:30:26 8 Devices.

17:30:26 9 A. Yes.

17:30:27 10 Q. That was around 2003 that you got your
17:30:29 11 directorship?

17:30:30 12 A. In devices? I came to devices around 2000,
17:30:34 13 2001.

17:30:34 14 Q. Okay. One of the first FDA directors that
17:30:36 15 you got to know real well while being a director in
17:30:40 16 devices would have been Mark McClellan; correct?

17:30:43 17 A. Right. I interacted with Dr. McClellan,
17:30:46 18 yes.

17:30:46 19 Q. Okay. He's the brother of the press
17:30:48 20 secretary, Scott McClellan; right?

17:30:51 21 A. He was.

17:30:51 22 Q. Okay. You'd agree with me that Mark
17:30:54 23 McClellan is somebody who is fairly well associated
17:30:57 24 with being a deregulation advocate; correct?

17:31:00 25 A. Oh, I didn't --

17:31:00 1 I wasn't part of the politics at my level at
17:31:03 2 that point in time.

17:31:04 3 Q. I mean you understood the fight of
17:31:05 4 deregulation in this country; correct?

17:31:08 5 A. Well those things waxed and waned depending
17:31:11 6 on who was in -- who was in the White House.

17:31:11 7 Q. Absolutely. And once somebody came into the
17:31:14 8 White House who was pro regulation, that's when you
17:31:16 9 left, basically.

17:31:17 10 A. Well I've been under so many
17:31:21 11 administrations, I -- I can't count them on two hands
17:31:22 12 any more.

17:31:22 13 Q. All right. Well let's move on from Mr.
17:31:25 14 McClellan. You remember Lester Crawford; right?

17:31:28 15 A. Sure.

17:31:28 16 Q. Okay. Now that's the commissioner who
17:31:31 17 resigned and was convicted of lying and violating
17:31:35 18 conflict-of-interest laws; right?

17:31:35 19 A. I don't recall the specifics, to tell you
17:31:35 20 the truth.

17:31:36 21 Q. Okay. Are you familiar with Andrew von
17:31:40 22 Eschenbach?

17:31:41 23 A. Yes.

17:31:42 24 Q. Now I'm sure from knowing Mr. Eschenbach and
17:31:45 25 what went down with his tenure, you know about the

17:31:47 1 Miniflex knee implant.

17:31:49 2 A. I have some knowledge, but not -- not
17:31:52 3 extensive knowledge of it.

17:31:52 4 Q. You understand he overruled subordinates
17:31:55 5 based on outside influences and ordered the approval
17:32:00 6 of the Miniflex knee implant?

17:32:00 7 A. I think there was an allegation in regard to
8 that.

9 Q. Now he runs some biotech and pharma
10 companies. Do you have any --

11 THE REPORTER: Just a minute.

17:32:05 12 MR. BANKSTON: Sure.

17:32:05 13 MS. EATON: And let me just object to the
17:32:08 14 form of that question first. I'm sorry.

17:32:08 15 A. I believe there were allegations in regard
17:32:10 16 to that.

17:32:11 17 Q. Now Mr. Eschenbach, he now runs some biotech
17:32:15 18 and pharma companies. Do you have any relationship
17:32:17 19 with those companies?

17:32:20 20 A. I have no idea what he's doing.

17:32:20 21 Q. Okay. The next administrator --

17:32:21 22 The next commissioner you had familiarity
17:32:23 23 with is Dr. Margaret Hamburg; correct?

17:32:25 24 A. Yes.

17:32:26 25 Q. Okay. She's the one who came in after the

17:32:28 1 change of administrations and launched the IOM

17:32:30 2 committee investigation; correct?

17:32:31 3 A. Actually, it was Dr. Jeff Shuren that

17:32:37 4 initiated the charge to the IOM and not -- and not Dr.

17:32:42 5 Hamburg.

17:32:42 6 Q. She was commissioner at that time; correct?

17:32:44 7 A. She was commissioner at the time.

17:32:46 8 Q. In other words, the -- the --

17:32:47 9 After the changing over of that

17:32:49 10 administration, there was an investigation launched by

17:32:52 11 the IOM committee into whether medical device approval

17:32:56 12 was doing a good job of protecting public safety.

17:32:58 13 A. Right. At points in time --

17:32:59 14 FDA is constantly under scrutiny in regard

17:33:02 15 to how it's functioning. It's -- it's probably on The

17:33:06 16 Hill more than any other agency.

17:33:07 17 Q. Now at the time that that report was

17:33:09 18 delivered, would you agree with me it was both

17:33:12 19 generally critical of 510(k) and specifically critical

17:33:15 20 of your division, that's when you left the FDA.

17:33:17 21 A. My division. I -- I don't understand.

17:33:20 22 Q. Correct. At that time when you --

17:33:22 23 MS. EATON: I'm sorry. And let me object to

17:33:24 24 the form of that question.

17:33:25 25 I -- I should not be reading while we're --

17:33:27 1 while you're talking.

17:33:28 2 Q. When you were in the FDA, when you left,
17:33:31 3 what was the last position you held?

17:33:32 4 A. The special advisor on enforcement --

17:33:35 5 Q. Okay.

17:33:37 6 A. -- to the commissioner.

17:33:37 7 Q. And before that you had had jobs in Centers
17:33:39 8 for Device and Radiological Health.

17:33:41 9 A. Correct.

17:33:42 10 Q. And that was specifically criticized by the
17:33:46 11 IOM report.

17:33:46 12 MS. EATON: Object to the form of the
17:33:46 13 question.

17:33:47 14 A. Well FDA's operations were criticized as
17:33:50 15 Center for Devices and its observations. There were
17:33:53 16 observations and findings made.

17:33:56 17 Q. Okay. I want to go back to the time of Mark
17:33:57 18 McClellan. Do you remember a deputy commissioner
17:34:00 19 named Scott Gottlieb?

17:34:01 20 A. Yes.

17:34:01 21 Q. Okay. Another --

17:34:04 22 Was that somebody you had regular
17:34:04 23 interactions with?

17:34:05 24 A. At that point in time, no, I wasn't high
17:34:07 25 enough to have frequent interactions with the guy.

17:34:11 1 Q. Have you had interactions with him since?

17:34:11 2 A. No.

17:34:12 3 Q. Okay. You understand he's a noted
17:34:14 4 deregulation advocate too; right?

17:34:16 5 MS. EATON: Object to the form of the
17:34:17 6 question.

17:34:17 7 A. He's not the commissioner though.

17:34:19 8 Q. Yeah. I mean that's not too controversial a
17:34:22 9 statement; right?

17:34:22 10 A. No. I -- I think that's -- that's the
17:34:24 11 general waxing and waning of -- of regulatory
17:34:27 12 agencies.

17:34:27 13 Q. And indeed that there has been, you will
17:34:30 14 agree over the last 17 years, some -- a lot of
17:34:34 15 fighting back and forth over what the role of the FDA
17:34:36 16 should be and what the role of medical device
17:34:39 17 regulation should be. You would agree with that?

17:34:42 18 A. No, I -- I wouldn't characterize it that
17:34:43 19 way. The -- the fundamental aspects of medical device
17:34:47 20 regulation are the same as they were in '76. There
17:34:51 21 have been modifications, but the statutory foundation
17:34:54 22 remain -- remains the same.

17:34:56 23 Q. You wouldn't agree with me that during two
17:34:59 24 of the administrations in which you were involved in
17:35:02 25 there was a serious em -- em -- emphasis to staff the

17:35:06 1 agency with people who were generally hostile or
17:35:09 2 skeptical of the agency's core goals?

17:35:11 3 A. No, I -- I wouldn't say that's the case.

4 Q. Okay.

17:35:13 5 A. Not -- not in the area where I worked, areas
17:35:15 6 where I worked.

17:35:18 7 MR. BANKSTON: You know what? I think --
17:35:20 8 yeah, I think that's all -- that's all the questions I
17:35:23 9 have for you today.

17:35:25 10 I'll reserve the right to continue the
17:35:26 11 deposition after a complete response to the subpoena:
17:35:31 12 notes, billings, articles, et cetera, that sort of
17:35:33 13 thing, but for the moment I'll go ahead and pass the
17:35:37 14 witness.

17:35:37 15 MS. EATON: Mr. Bankston, there is no
17:35:39 16 incomplete response to the subpoena. There's answers
17:35:41 17 with respect to everything. And I did provide you
17:35:44 18 over the lunch break with the May 2017 invoice.

17:35:46 19 MR. BANKSTON: If I get anything else, I
17:35:49 20 might want to redepose him, that's all I'm putting on
17:35:56 21 the record.

17:35:56 22 MS. EATON: We'll go off for a moment.

17:35:59 23 THE REPORTER: Off the record, please.

17:36:00 24 (Recess taken.)

17:50:17 25 MS. EATON: Can you mark that for me.

17:50:29 1 (Ulatowski Exhibit 10 was marked for
17:50:32 2 identification.)

17:50:32 3 MS. EATON: Thank you.

17:50:32 4 REDIRECT EXAMINATION

17:50:32 5 BY MS. EATON:

17:50:33 6 Q. Mr. Ulatowski, I've marked as Exhibit 10 an
17:50:35 7 invoice for your work on this litigation and related
17:50:39 8 to this report in May of 2017; is that correct?

17:50:42 9 A. Yes.

17:50:44 10 MS. EATON: And Ms. Zimmerman, you would
17:50:46 11 agree that this is a document I handed to Mr. Bankston
17:50:50 12 over the lunch break; is that right?

17:50:51 13 MS. ZIMMERMAN: Yes.

17:50:53 14 MS. EATON: Thank you. We just needed to
17:50:55 15 put that on the record.

17:50:57 16 Q. Mr. Ulatowski, how much time is reflected on
17:50:59 17 this invoice?

17:51:01 18 A. For May, 69 and a quarter hours.

17:51:06 19 Q. Was that time spent in relation to the
17:51:09 20 review and report that we have been discussing here
17:51:12 21 today?

17:51:13 22 A. Yes.

17:51:14 23 MS. EATON: Okay. And I will just state for
17:51:17 24 the record that that invoice came to me by e-mail on
17:51:19 25 Friday when I was traveling and I did not see it, so

17:51:22 1 that's why I was prompted by the discussion this
17:51:25 2 morning to look for it and produce it.

17:51:32 3 Q. Mr. Ulatowski, in preparing your report and
17:51:35 4 expressing your opinions in this litigation, have you
17:51:38 5 used any information that you gained during your time
17:51:40 6 at FDA about the blood fluid warmer?

17:51:44 7 A. No.

17:51:45 8 MS. ZIMMERMAN: Object to form.

17:51:46 9 Q. Have you used --

17:51:47 10 MS. EATON: What is the objection?

17:51:49 11 MS. ZIMMERMAN: It's leading.

17:51:52 12 MS. EATON: I don't think I could make it
17:51:53 13 any less leading.

17:51:55 14 Q. Have you used any information that you
17:51:56 15 gained during your time at FDA in expressing your
17:51:59 16 opinions in this case?

17:52:01 17 A. Just my experience with regulations.

17:52:03 18 Q. I'm sorry. Specific to the devices at
17:52:05 19 issue.

17:52:06 20 A. No.

17:52:07 21 MS. EATON: Okay. I would like to mark
17:52:10 22 this.

17:52:27 23 (Ulatowski Exhibit 11 was marked for
24 identification.)

17:52:32 25 BY MS. EATON:

17:52:32 1 Q. Is Ulatowski Exhibit 11 the ECRI statement
17:52:39 2 that we have -- that you have been discussing here
17:52:40 3 today?

17:52:41 4 A. Yes.

17:52:42 5 Q. Is Exhibit 11 a document that you reviewed
17:52:46 6 in the course of your work on this case?

17:52:49 7 A. Yes.

17:52:49 8 Q. Is Exhibit 11 a document that you cited in
17:52:51 9 your report?

17:52:51 10 A. Yes.

17:52:52 11 Q. Could you please turn to the third page of
17:52:54 12 Exhibit 11.

17:53:02 13 A. Okay.

17:53:02 14 Q. I'm sorry, perhaps I meant the fourth page.
17:53:04 15 I want the page that has "CONCLUSIONS." Thank you.

17:53:07 16 You see that there's a few paragraphs under
17:53:11 17 the heading "CONCLUSIONS?"

17:53:12 18 A. Yes.

17:53:12 19 Q. Could you please just read for us what those
17:53:15 20 paragraphs state.

17:53:16 21 A. "Based on our focused systematic review of
17:53:20 22 the published literature, we believe that there is
17:53:23 23 insufficient evidence to establish that the use of
17:53:27 24 forced-air warming systems leads to an increase in
17:53:32 25 surgical-site infections compared to other warming

17:53:37 1 methods. Although one study (McGovern et al.)
17:53:43 2 presents data that suggests higher PJI rates with use
17:53:51 3 of forced-air warming compared to an alternative
17:53:54 4 warming method, this study has serious limit --
17:53:57 5 limitations such that its findings on PJI rates cannot
17:54:02 6 be considered conclusive. Studies that look at
17:54:05 7 forced-air warming's contribution to operating room
17:54:09 8 air contamination and/or airflow disruption raise
17:54:13 9 questions about the technology and its potential
17:54:16 10 impact, but they do not provide sufficient evidence to
17:54:19 11 demonstrate that the use of forced-air warming poses a
17:54:23 12 greater risk of" -- I'll use the acronym -- "SSIs or
17:54:28 13 PJIs than the use of other warming methods.

17:54:31 14 "Consequently, ECRI Institute does not
17:54:34 15 believe that the currently available evidence
17:54:37 16 justifies discontinuing the use of FAW during surgery.
17:54:43 17 We will continue to monitor this topic through the
17:54:46 18 published literature and will update our
17:54:49 19 recommendation as warranted."

17:54:51 20 Q. Was that information important to you in
17:54:54 21 your review of this case?

17:54:55 22 A. Yes, and -- and I included it in my report.

17:54:59 23 Q. How was that information relevant to the
17:55:01 24 opinions you expressed in this case?

17:55:03 25 A. Well it's an independent organization

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17:55:05 1 commenting on their analysis of the -- of the data at
17:55:10 2 that point in time, in 2013, concerning the issues at
17:55:14 3 hand in this litigation.

17:55:16 4 Q. Could you please turn to page 43 of your
17:55:18 5 report.

17:55:29 6 A. Okay.

17:55:30 7 Q. Nearly at the very bottom of the page you
17:55:36 8 give the opinion that --

17:55:40 9 I'm sorry. Let me start over.

17:55:40 10 Near the bottom of page 43 you express the
17:55:43 11 opinion that you have bases -- four bases for
17:55:55 12 substantial --

17:55:56 13 I'm sorry. Let me start over.

17:55:57 14 Really, what I want to ask about is subpart
17:56:02 15 one. "There are no publications prior to or after the
17:56:05 16 Model 750 was cleared by FDA that have verified the
17:56:08 17 infection related to any Bair Hugger regardless of
17:56:10 18 filter media." That is the sentence I would like you
17:56:12 19 to focus on. Have I read that correctly?

17:56:15 20 A. Yes.

17:56:16 21 Q. Did you review the literature with respect
17:56:20 22 to whether people had reported an increased risk of
17:56:27 23 infection caused by the use of the Bair Hugger device?

17:56:32 24 A. In regard to the literature?

17:56:34 25 Q. Did you review the literature to see if

17:56:36 1 anyone had reported an increased risk of infection
17:56:40 2 that they attributed to the use of the Bair Hugger
17:56:42 3 device?

17:56:43 4 A. Yes. I looked at all -- all the literature
17:56:45 5 and the implications of the Bair Hugger and the -- the
17:56:52 6 postulations, I'll call them, that infection rates
17:56:56 7 were related, but as a -- as a -- as a portion of some
17:57:00 8 of the -- some of the studies.

17:57:02 9 Q. Did the study authors that you reviewed
17:57:05 10 conclude that their individual studies did not
17:57:09 11 establish a causal relationship between use of the
17:57:11 12 Bair Hugger device and any increased infection risk?

17:57:14 13 A. Right. That was ultimately the -- the
17:57:17 14 conclusion -- or the finding because of the nature of
17:57:23 15 the studies that -- that one -- neither --

17:57:24 16 None of the studies could conclusively draw
17:57:26 17 that direct linkage from infections to the Bair
17:57:30 18 Hugger.

17:57:31 19 Q. Was that important to the work that you did
17:57:35 20 and the opinions that you expressed in this case?

17:57:37 21 A. Yes. It's certainly relevant and -- and not
17:57:40 22 surprising.

17:57:42 23 Q. Okay. If you could turn to page 78 of your
17:57:45 24 report.

17:57:48 25 A. Okay.

17:57:50 1 Q. On page 78 you are discussing a warning
17:57:55 2 letter that was sent by the FDA to Augustine
17:58:00 3 Biomedical & Design; correct?

17:58:00 4 A. Yes.

17:58:06 5 Q. Is this discussion relevant to your review
17:58:11 6 of Dr. David's expressed opinions and your response to
17:58:14 7 those opinions?

17:58:15 8 A. Yes, because the -- the claims being made by
17:58:22 9 Dr. Augustine in -- his comparative claims between his
17:58:30 10 technology and forced-air warming, and the fact that
17:58:35 11 FDA determined that his claims were without foundation
17:58:40 12 and -- and so asked him to eliminate those claims from
17:58:45 13 his products.

17:58:46 14 Q. Were the claims that Dr. Augustine was
17:58:50 15 making related to airborne contamination and infection
17:58:54 16 risk?

17:58:56 17 A. Yes. He stated Bair Hugger contaminates the
17:58:59 18 sterile field, so on and so forth, in his claims.

17:59:02 19 Q. On this page do you also cite the literature
17:59:05 20 and the ECRI analysis that we just discussed?

17:59:08 21 A. Yes.

17:59:08 22 Q. Have you expressed any opinion in this
17:59:17 23 report concerning how particulate emission relates to
17:59:20 24 infection risk from a scientific or medical
17:59:23 25 perspective?

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17:59:24 1 A. No.

17:59:24 2 Q. Have you focused your review of Dr. David's
17:59:27 3 report and your response to his report on regulatory
17:59:30 4 issues?

17:59:30 5 A. That was the focus.

17:59:31 6 Q. Have you focused your review of the punitive
17:59:35 7 damages motion and any response you made to that to
17:59:38 8 regulatory issues?

17:59:40 9 A. That was my focus.

17:59:41 10 Q. When you reviewed the punitive damages
17:59:46 11 motion, were you also focused on those things that
17:59:48 12 related to any opinions you had expressed?

17:59:51 13 A. Well yes.

17:59:51 14 MS. ZIMMERMAN: I'm going to object to form
17:59:53 15 to the extent that this witness has been identified as
17:59:55 16 a witness who has rebutting testimony. Any kind of
17:59:59 17 legal argument that is made in a punitive damages
18:00:00 18 motion is outside the scope of any report that he has
18:00:03 19 prepared or ought to be prepared and will be
18:00:05 20 considered in this court.

18:00:10 21 Q. Did you include in your report only opinions
18:00:12 22 that you felt qualified to express?

18:00:14 23 A. Yes.

18:00:14 24 Q. Did you include in your report the bases
18:00:17 25 that you felt were important and required to support

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18:00:21 1 your opinions?

18:00:21 2 A. I believe so.

18:00:22 3 MS. EATON: That's all I have.

18:00:24 4 THE REPORTER: Off the record, please.

18:00:27 5 (Deposition concluded.)

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1 C E R T I F I C A T E

2 I, Richard G. Stirewalt, hereby certify that
3 I am qualified as a verbatim shorthand reporter, that
4 I took in stenographic shorthand the deposition of
5 TIMOTHY A. ULATOWSKI at the time and place aforesaid,
6 and that the foregoing transcript is a true and
7 correct, full and complete transcription of said
8 shorthand notes, to the best of my ability.

9 Dated at Deerwood, Minnesota, this 14th day
10 of July, 2017.

11

12

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16

17 RICHARD G. STIREWALT

18 Registered Professional Reporter

19 Notary Public

20

21

22

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25

1 C E R T I F I C A T E

2 I, TIMOTHY A. ULATOWSKI, hereby certify that
 3 I have carefully read the foregoing transcript, and
 4 that the same is a true and complete, full and correct
 5 transcription of my deposition, except:

6 PAGE/LINE CHANGE REASON

7

8

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10

11

12

13

14

15

16

17 TIMOTHY A. ULATOWSKI

18 Deponent

19

20 Signed and sworn to before me this ____ day of
 21 August, 2017.

22

23

24 Notary Public

25

EXHIBIT DX6

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 1996

Scott D. Augustine, M.D., CEO
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, Minnesota 55344

Re: K960167
Bair Hugger Model 505 Warming Unit/Bair Hugger Blankets
Regulatory Class: II (Two)
Product Code: 74DWJ
Dated: May 10, 1996
Received: May 14, 1996

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

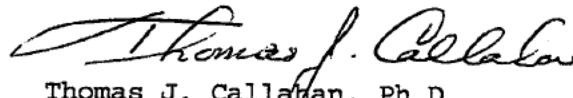
3MBH00047138

Page 2 - Scott D. Augustine, M.D., CEO

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597.

Sincerely yours,



Thomas J. Callahan, Ph.D.

Director

Division of Cardiovascular, Respiratory,
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

3MBH00047139

EXHIBIT DX7

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP - 6 2000

Augustine Medical
c/o David Westlin
Director of Regulatory Affairs and
Quality Assurance
10393 West 70th Street
Eden Prairie, MN 55344

Re: K001149
The Bair Hugger® Model 750 Total Temperature
Management® System
Regulatory Class: II Two
Product Code: DWJ
Dated: July 19, 2000
Received: July 21, 2000

Dear Mr. Westlin:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this

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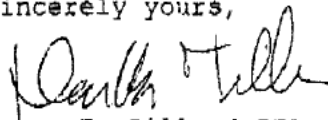
Page 2 - Mr. David Westlin

response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

for 

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

3MBH00046941

EXHIBIT DX8

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

Premarket Notification 510(k)

- [Introduction](#)
- [What is Substantial Equivalence](#)
- [Who is Required to Submit a 510\(k\)](#)
- [When a 510\(k\) is Required](#)
- [When a 510\(k\) is not Required](#)
- [Preamendment Devices](#)
- [Third Party Review Program](#)

Please note: [FDA charges a fee for review of Premarket Notifications \[510\(k\)\]](#)
[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm540444.htm\)](#)

Introduction

Each person who wants to market in the U.S., a Class I, II, and III device intended for human use, for which a Premarket Approval (PMA) is not required, must submit a 510(k) to FDA unless the device is exempt from 510(k) requirements of the Federal Food, Drug, and Cosmetic Act (the Act) and does not exceed the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9). There is no 510(k) form, however, [21 CFR 807 \(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5\)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5). Subpart E describes requirements for a 510(k) submission. Before marketing a device, each submitter must receive an order, in the form of a letter, from FDA which finds the device to be substantially equivalent (SE) and states that the device can be marketed in the U.S. This order "clears" the device for commercial distribution.

A 510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent, to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA. Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. A legally marketed device, as described in 21 CFR 807.92(a)(3), is a device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The legally marketed device(s) to which equivalence is drawn is commonly known as the "predicate." Although devices recently cleared under 510(k) are often selected as the predicate to which equivalence is claimed, any legally marketed device may be used as a predicate. Legally marketed also means that the predicate cannot be one that is in violation of the Act.

Until the submitter receives an order declaring a device SE, the submitter may not proceed to market the device. Once the device is determined to be SE, it can then be marketed in the U.S. The SE determination is usually made within 90 days and is made based on the information submitted by the submitter.

Please note that FDA does not perform 510(k) pre-clearance facility inspections. The submitter may market the device immediately after 510(k) clearance is granted. The manufacturer should be prepared for an FDA quality system (21 CFR 820) inspection at any time after 510(k) clearance.

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What is Substantial Equivalence

A 510(k) requires demonstration of substantial equivalence to another legally U.S. marketed device. Substantial equivalence means that the new device is at least as safe and effective as the predicate.

A device is substantially equivalent if, in comparison to a predicate it:

- has the same intended use as the predicate; **and**

- has the same technological characteristics as the predicate;
or
- has the same intended use as the predicate; **and**
- has different technological characteristics and the information submitted to FDA;
 - does not raise new questions of safety and effectiveness; **and**
 - demonstrates that the device is at least as safe and effective as the legally marketed device.

A claim of substantial equivalence does not mean the new and predicate devices must be identical. Substantial equivalence is established with respect to intended use, design, energy used or delivered, materials, chemical composition, manufacturing process, performance, safety, effectiveness, labeling, biocompatibility, standards, and other characteristics, as applicable.

A device may not be marketed in the U.S. until the submitter receives a letter declaring the device substantially equivalent. If FDA determines that a device is **not** substantially equivalent, the applicant may:

- resubmit another 510(k) with new data,
- request a Class I or II designation through the **de novo**
[/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm462775.htm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=860&showFR=1&subpartNode=21.8.0.1.1.15.3) process
- file a **reclassification petition** (<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=860&showFR=1&subpartNode=21.8.0.1.1.15.3>), or
- submit a premarket approval application (PMA).

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Who is Required to Submit a 510(k)

The Act and the 510(k) regulation (21 CFR 807) do not specify who must apply for a 510(k). Instead, they specify which actions, such as introducing a device to the U.S. market, require a 510(k) submission.

The following four categories of parties must submit a 510(k) to the FDA:

1. Domestic manufacturers introducing a device to the U.S. market;

Finished device manufacturers must submit a 510(k) if they manufacture a device according to their own specifications and market it in the U.S. Accessories to finished devices that are sold to the end user are also considered finished devices. However, manufacturers of device components are not required to submit a 510(k) unless such components are promoted for sale to an end user as replacement parts. Contract manufacturers, those firms that manufacture devices under contract according to someone else's specifications, are not required to submit a 510(k).

2. Specification developers introducing a device to the U.S. market;

A specification developer develops the specifications for a finished device, but has the device manufactured under contract by another firm or entity. The specification developer submits the 510(k), not the contract manufacturer.

3. Repackagers or relabelers who make labeling changes or whose operations significantly affect the device.

Repackagers or relabelers may be required to submit a 510(k) if they significantly change the labeling or otherwise affect any condition of the device. Significant labeling changes may include modification of manuals, such as adding a new intended use, deleting or adding warnings, contraindications, etc. Operations, such as sterilization, could alter the condition of the device. However, most repackagers or relabelers are not required to submit a 510(k).

4. Foreign manufacturers/exporters or U.S. representatives of foreign manufacturers/exporters introducing a device to the U.S. market.

Please note that all manufacturers (including specification developers) of Class II and III devices and select Class I devices are required to follow design controls (21 CFR 820.30) during the development of their device. The holder of a 510(k) must have design control documentation available for FDA review during a site inspection. In addition, any changes to the device specifications or manufacturing processes must be made in accordance with the Quality System regulation (21 CFR 820) and may be subject to a new 510(k). Please see our guidance, "[Deciding When to Submit a 510\(k\) for a Change to an Existing Device](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=860&showFR=1&subpartNode=21.8.0.1.1.15.3)" ([/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=860&showFR=1&subpartNode=21.8.0.1.1.15.3))."



When a 510(k) is Required

A 510(k) is required when:

1. Introducing a device into commercial distribution (marketing) for the first time. After May 28, 1976 (effective date of the Medical Device Amendments to the Act), anyone who wants to sell a device in the U.S. is required to make a 510(k) submission at least 90 days prior to offering the device for sale, even though it may have been under development or clinical investigation before that date. If your device was not marketed by your firm before May 28, 1976, a 510(k) is required.
2. You propose a different intended use for a device which you already have in commercial distribution. The 510(k) regulation (**21 CFR 807 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=807&showFR=1&subpartNode=21:8.0.1.1.5.5)**) specifically requires a 510(k) submission for a major change or modification in intended use. Most, if not all changes in intended use will require a 510(k). Please note that prescription use to over the counter use is a major change in intended use and requires the submission of a new 510(k).
3. There is a change or modification of a legally marketed device and that change could significantly affect its safety or effectiveness. The burden is on the 510(k) holder to decide whether or not a modification could significantly affect safety or effectiveness of the device. Any modifications must be made in accordance with the Quality System regulation, 21 CFR 820, and recorded in the device master record and change control records. It is recommended that the justification for submitting or not submitting a new 510(k) be recorded in the change control records.

A new 510(k) submission is required for changes or modifications to an existing device, where the modifications could significantly affect the safety or effectiveness of the device or the device is to be marketed for a new or different indication for use. See **Is a new 510(k) required for a modification to the device? (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134575.htm)** for additional information.



When a 510(k) is Not Required

The following are examples of when a 510(k) is not required.

1. You sell unfinished devices to another firm for further processing or sell components to be used in the assembling of devices by other firms. However, if your components are to be sold directly to end users as replacement parts, a 510(k) is required.
2. Your device is not being marketed or commercially distributed. You do not need a 510(k) to develop, evaluate, or test a device. This includes clinical evaluation. Please note that if you perform clinical trials with your device, you are subject to the **Investigational Device Exemption (/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/InvestigationalDeviceExemptionIDE/default.htm)** (IDE) regulation (21 CFR 812).
3. You distribute another firm's domestically manufactured device. You may place a label on the device, "Distributed by ABC Firm" or "Manufactured for ABC Firm," (**21 CFR 801.1 (http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=801.1)**) and sell it to end users without submission of a 510(k).
4. In most cases, if you are a repackager or a relabeler you are not required to submit a 510(k) if the existing labeling or condition of the device is not significantly changed. The labeling should be consistent with the labeling submitted in the 510(k) with the same indications for use and warnings and contraindications.
5. Your device was legally in commercial distribution before May 28, 1976 and you have documentation to prove this. These devices are "grandfathered" and have **Preamendment Status (/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm)**. You do not have to submit a 510(k) unless the device has been significantly modified or there has been a change in its intended use.
6. The device is made outside the U.S. and you are an importer of the foreign made medical device. A 510(k) is not required if a 510(k) has been submitted by the foreign manufacturer and received marketing clearance. Once the foreign manufacturer has received 510(k) clearance for the device, the foreign manufacturer may export his device to any U.S. importer.

7. Your device is exempted from 510(k) by regulation (21 CFR 862-892). That is, certain Class I or II devices can be marketed for the first time without having to submit a 510(k). A list of the Class I and II exempted devices can be found on [Medical Device Exemptions 510\(k\) and GMP Requirements \(http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm\)](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpd/315.cfm). However, if the device exceeds the limitations of exemptions in .9 of the device classification regulation chapters (e.g., 21 CFR 862.9, 21 CFR 864.9), such as the device has a new intended use or operates using a different fundamental scientific technology than a legally marketed device in that generic type of device, or the device is a reprocessed single-use device, then a 510(k) must be submitted to market the new device.

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Preamendment Devices

The term "preamendments device" refers to devices legally marketed in the U.S. by a firm before May 28, 1976 **and** which have not been:

- significantly changed or modified since then; **and**
- for which a regulation requiring a PMA application has not been published by FDA.

Devices meeting the above criteria are referred to as "grandfathered" devices and do not require a 510(k). The device must have the same intended use as that marketed before May 28, 1976. If the device is labeled for a new intended use, then the device is considered a new device and a 510(k) must be submitted to FDA for marketing clearance.

Please note that you must be the **owner** of the device on the market before May 28, 1976, for the device to be grandfathered. If your device is similar to a grandfathered device and marketed **after** May 28, 1976, then your device does NOT meet the requirements of being grandfathered and you must submit a 510(k). In order for a firm to claim that it has a preamendments device, it must demonstrate that its device was labeled, promoted, and distributed in interstate commerce for a specific intended use and that intended use has not changed.

See [Preamendment Status](#)

[\(/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm\)](http://www.fda.gov/medicaldevices/deviceregulationandguidance/medicaldevicequalityandcompliance/ucm379552.htm) for information on documentation requirements.

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Third Party Review Program

The Center for Devices and Radiological Health (CDRH) has implemented a Third Party Review Program. This program provides an option to manufacturers of certain devices of submitting their 510(k) to private parties (Recognized Third Parties) identified by FDA for review instead of submitting directly to CDRH. For more information on the program, eligible devices and a list of Recognized Third Parties go to

[Third Party Review Program Information](#)

[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ThirdPartyReview/default.htm\)](http://www.fda.gov/medicaldevices/deviceregulationandguidance/howtomarketyourdevice/premarket submissions/thirdpartyreview/default.htm) page.

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References

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- [New Section 513\(f\)\(2\) - Evaluation of Automatic Class III Designation, Guidance for Industry and CDRH Staff \(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080195.htm\)](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm080195.htm)
- [510\(k\) Decision-Making Flowchart \(http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf#page=30\)](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf#page=30)
- [The 510\(k\) Program: Evaluating Substantial Equivalence in Premarket Notifications \[510\(k\)\] - Guidance for Industry and Food and Drug Administration Staff \(PDF - 844KB\) \(/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf\)](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM284443.pdf)

- **[Deciding When to Submit a 510\(k\) for a Change to an Existing Device \(K97-1\)](#)**
[\(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080235.htm\)](#)

Additional Information

- **[510\(k\) Clearances \(/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm\)](#)**

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[510\(k\) Submission Methods](#)
[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134034.htm\)](#)

[How To Prepare A Special 510\(k\)](#)
[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134573.htm\)](#)

[How to Find and Effectively Use Predicate Devices](#)
[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134571.htm\)](#)

[How to Prepare a Traditional 510\(k\)](#)
[\(/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm134572.htm\)](#)

[How to Prepare an Abbreviated 510\(k\)](#)
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EXHIBIT DX9

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

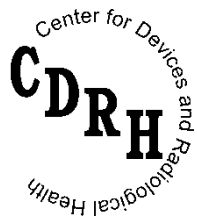
Document issued on: July 28, 2014

The draft of this document issued on December 27, 2011.

**This document supersedes FDA's Guidance on the CDRH Premarket Notification
Review Program, 510(k) Memorandum K86-3, dated June 30, 1986.**

For questions for the Center for Devices and Radiological Health regarding this document, contact the
Premarket Notification (510(k)) Section at 301-796-5640.

For questions for the Center for Biologics Evaluation and Research regarding this document, contact the
Office of Communication, Outreach and Development at 1-800-335-4709 or 240-402-7800.



**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Center for Biologics Evaluation and Research**

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Preface

Public Comment

You may submit electronic comments and suggestions at any time for Agency consideration to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management, Food and Drug Administration, 5630 Fishers Lane, Room. 1061, (HFA-305), Rockville, MD, 20852. Identify all comments with the docket number FDA-2011-D-0652. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Additional copies are available from the Internet. You may also send an e-mail request to CDRH-Guidance@fda.hhs.gov to receive a copy of the guidance. Please use the document number 1766 to identify the guidance you are requesting.

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The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]

Guidance for Industry and Food and Drug Administration Staff

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. Introduction

FDA developed this document to provide guidance to industry and FDA staff about current review practices for premarket notification (510(k)) submissions. The intent of this guidance is to identify, explain, and clarify each of the critical decision points in the decision-making process FDA uses to determine substantial equivalence. This guidance is not intended to implement significant policy changes to the current 510(k) review process. Rather, the intent of this guidance is to enhance the predictability, consistency, and transparency of the 510(k) program by describing in greater detail the regulatory framework, policies, and practices underlying FDA's 510(k) review.

The draft of this guidance document contained sections addressing FDA's Special and Abbreviated 510(k) programs. FDA intends to finalize those sections separately. Until FDA issues new final recommendations on the Special and Abbreviated 510(k) programs, the recommendations for Special and Abbreviated 510(k)s contained in "[The New 510\(k\) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm)," dated March 20, 1998, (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080187.htm>) remain in effect.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

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II. Background

A. The Medical Device Amendments and Device Classification

The Medical Device Amendments (MDA) (Pub. L. 94-295) to the Federal Food, Drug, and Cosmetic (FD&C) Act were enacted on May 28, 1976. The MDA directed FDA to issue regulations that classify all devices that were in commercial distribution at that time into one of three regulatory control categories: Class I, II, or III, depending upon the degree of regulation necessary to provide reasonable assurance of their safety and effectiveness. The class into which a device is placed determines the requirements that a medical device manufacturer must meet prior to distributing a device in interstate commerce. According to section 513(a)(1) of the FD&C Act (21 U.S.C. § 360c(a)(1)), the three device classes are defined as follows:

- **Class I:** Devices are subject to a comprehensive set of regulatory authorities called general controls that are applicable to all classes of devices.¹
- **Class II:** Devices for which general controls, by themselves, are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance.²
- **Class III:** Devices for which general controls, by themselves, are insufficient and for which there is insufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device. Class III devices typically require premarket approval.³

Premarket notification is the process by which a new device,⁴ i.e., a post-amendments device, is classified into one of these three device classes.⁵ A manufacturer who intends to market in the United

¹ General controls apply to all classes of medical devices and provide FDA with the means of regulating devices to assure their safety and effectiveness. General controls include but are not limited to provisions that relate to establishment registration and device listing; premarket notification, although most class I devices are exempt by regulation from this requirement; prohibitions against adulteration and misbranding; records and reports; and good manufacturing practices. Section 513(a)(1)(A) of the FD&C Act (21 U.S.C. § 360c(a)(1)(A)).

² The original definition of a class II device in the Medical Device Amendments of 1976 (Pub. L. 94-295) identified performance standards rather than special controls as the mechanism by which FDA could establish reasonable assurance of safety and effectiveness. The Safe Medical Devices Act of 1990 (Pub. L. 101-629) added “special controls,” which can include the promulgation of performance standards as well as postmarket surveillance, patient registries, development and dissemination of guidelines (including guidelines for the submission of clinical data in premarket notification submissions), and other appropriate actions as FDA deems necessary to provide such assurance. Section 513(a)(1)(B) of the FD&C Act (21 U.S.C. § 360c(a)(1)(B)).

³ Certain types of devices classified into class III that were in commercial distribution in the United States before May 28, 1976, and those determined to be substantially equivalent to such devices, may be cleared through the 510(k) process until FDA issues an administrative order requiring them to go through the premarket approval process. Section 515(b)(1) of the FD&C Act (21 U.S.C. § 360e(b)(1)). Prior to the enactment of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144) on July 9, 2012, FDA had to publish regulations to require such devices to go through the premarket approval process. Section 608(b) of FDASIA (126 Stat. 1056) changed the process from rulemaking to administrative order.

⁴ For the purpose of this guidance document, a “new device” means a device within the meaning of section 201(h) of the FD&C Act that is not legally marketed. It can be either a completely new device or a modification of a legally marketed device that would require a new 510(k).

⁵ By contrast, an unclassified devices, as defined in FDA’s Guidance for Industry and Food and Drug Administration Staff, “[Medical Device Classification Product Codes](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm>), is a pre-amendments

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States a Class I, II, or III device intended for human use, for which a Premarket Approval application (PMA) is not required, must submit to FDA a premarket notification submission (often referred to as a 510(k)), unless the device is exempt from the 510(k) requirements of the FD&C Act and does not exceed the limitations of exemptions for each of the device classification regulations (Section .9 of 21 CFR Parts 862 through 892, e.g., 21 CFR 862.9, 21 CFR 864.9, etc.). Under section 510(k) of the FD&C Act, a manufacturer must submit a 510(k) to FDA at least 90 days before introducing, or delivering for introduction, a device into interstate commerce for commercial distribution so the Agency can determine whether or not the device meets the criteria for market clearance (Sections 510(k) and (n) of the FD&C Act (21 U.S.C. §§ 360(k) & (n))). The Agency bases its decision on whether the device is substantially equivalent (SE) to a legally marketed (predicate) device (Section 513(i) of the FD&C Act (21 U.S.C. § 360c(i))). The device cannot be commercialized until FDA issues an order (510(k) clearance) stating that the device has been determined to be SE (Section 513(f)(1) of the FD&C Act (21 U.S.C. § 360c(f)(1))).

B. The 510(k) Classification Process

According to section 513(f) of the FD&C Act, a new (i.e., post-amendments) device is automatically in Class III and must undergo premarket approval or reclassification before it can be marketed, unless it is a type of device that was in commercial distribution prior to May 28, 1976, and is SE to another such device; or it is within a type of device introduced after May 28, 1976, that has been reclassified into Class I or II and is SE to another device within such classification. For information about how FDA's classification product codes assist in accurate identification and tracking of current medical devices, please see FDA's Guidance for Industry and Food and Drug Administration Staff, "[Medical Device Classification Product Codes](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm285317.htm>).

When FDA determines under sections 510(k), 513(f)(1), and 513(i) of the FD&C Act that a new device is SE to a legally marketed (predicate) device, the new device is classified into the same class and subject to the same requirements as the predicate device. (See **Section IV.C.**) A determination that a new device is not substantially equivalent (NSE) to a predicate device results in the new device being classified into Class III. Thus, 510(k) review is both the mechanism by which a manufacturer seeks marketing authorization for a new device and by which FDA classifies devices into their appropriate regulatory category. Because devices are classified according to the level of regulatory control necessary to provide a reasonable assurance of safety and effectiveness,⁶ classification of a

device for which a classification regulation has not been promulgated. Unclassified devices require submission of a 510(k) premarket notification to FDA. A not-classified device is a post-amendments device for which the Agency has not yet reviewed a marketing application or for which the Agency has not made a final decision on such a marketing application. A pre-amendments device is a device that was on the market prior to the enactment of the Medical Device Amendments to the FD&C Act on May 28, 1976.

⁶ The three device classes are described in section 513(a) of the FD&C Act (21 U.S.C. § 360c(a)):

(1) There are established the following classes of devices intended for human use:

(A) CLASS I, GENERAL CONTROLS.—

(i) A device for which the controls . . . are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

(ii) A device for which insufficient information exists to determine that the controls referred to in clause (i) are sufficient to provide reasonable assurance of the safety and effectiveness of the device or to establish special controls to provide such assurance, but because it—

(I) is not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and

(II) does not present a potential unreasonable risk of illness or injury, is to be regulated by the controls referred to in clause (i).

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new device through the 510(k) process requires FDA to determine the issues of safety and effectiveness presented by the new device, and the regulatory controls necessary to address those issues.⁷

C. Evolution of the 510(k) Program

Since its inception, the 510(k) program has undergone a number of statutory changes. Notably, the Safe Medical Devices Act of 1990 (Pub. L. 101-629) added section 513(i), which codified FDA review practice in applying the “substantial equivalence” review standard. In addition, FDA has modified its implementation of the program to adapt to changing circumstances and to accommodate the evolving medical device landscape. For example, the alternative options of a Special 510(k) or an Abbreviated 510(k) still exist today. Additional information regarding these alternative options can be found in FDA’s guidance, “[The New 510\(k\) Paradigm – Alternative Approaches to Demonstrating Substantial Equivalence in Premarket Notifications](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf)” (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080189.pdf>). The current 510(k) program reflects the current statutory framework and FDA’s implementation of that framework through regulation, guidance, and administrative practice. A history of the 510(k) program has been summarized in other documents that FDA has published.⁸

This guidance document provides updated information to the existing guidance document entitled “Guidance on the CDRH Premarket Notification Review Program, 510(k) Memorandum K86-3” (K86-3 Guidance), issued on June 30, 1986. The K86-3 Guidance was written and issued as final guidance prior to the February 27, 1997 implementation of FDA’s Good Guidance Practices (GGPs), and has not been updated since its initial publication date. This guidance replaces the K86-3 Guidance.

(B) CLASS II, SPECIAL CONTROLS.—A device which cannot be classified as a class I device because the general controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device, and for which there is sufficient information to establish special controls to provide such assurance . . .

(C) CLASS III, PREMARKET APPROVAL.—A device which because—

- (i) it (I) cannot be classified as a class I device because insufficient information exists to determine that the application of general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device, and (II) cannot be classified as a class II device because insufficient information exists to determine that the special controls described in subparagraph (B) would provide reasonable assurance of its safety and effectiveness, and
 - (ii)(I) is purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, or
 - (II) presents a potential unreasonable risk of illness or injury,
- is to be subject, in accordance with section 515, to Premarket approval to provide reasonable assurance of its safety and effectiveness.

⁷ If FDA has established special controls applicable to the device type, the 510(k) would need to adequately address the issues covered by the special controls for the device to be classified into Class II. See Section 513(a)(1)(B) of the FD&C Act (21 U.S.C. § 360c(a)(1)(B)).

⁸ See [CDRH Preliminary Internal Evaluations – Volume I: 510\(k\) Working Group Preliminary Report and Recommendations](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf) (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220784.pdf>). See also [CDRH Preliminary Internal Evaluations – Volume II: Task Force on the Utilization of Science in Regulatory Decision Making Preliminary Report and Recommendations](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220783.pdf) (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM220783.pdf>). See also [510\(k\) and Science Report Recommendations: Summary and Overview of Comments and Next Steps](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf) (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf>).

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III. Scope

This guidance provides recommendations to industry and FDA staff about the content of 510(k) submissions and the decision-making process for determining substantial equivalence of devices reviewed under the 510(k) program. The guidance has been organized to coincide with the critical decision points outlined in the 510(k) Decision-Making Flowchart (See **Appendix A**), which has been updated to track section 513(i) of the FD&C Act and relevant regulations more closely. This document provides guidance on the following issues:

- the appropriate use of multiple predicates (See Section IV.C);
- the processes associated with determining whether a new device with new indications for use has a new intended use (See Section IV.D);
- the process for determining whether different technological characteristics raise different questions of safety and effectiveness (See Section IV.E);
- when performance data, with special emphasis on clinical performance data, may be necessary to support an SE determination (See Section IV.F); and
- how to develop 510(k) Summaries to promote greater transparency in the 510(k) decision-making process (See Section IV.G).

The overarching principles in this guidance are applicable to devices that are subject to 510(k) review by CDRH, including the Office of Device Evaluation (ODE) and the Office of In Vitro Diagnostics and Radiological Health (OIR), as well as devices that are subject to 510(k) review by the Center for Biologics Evaluation and Research (CBER). This guidance is not intended to supplant existing device-specific guidance, but may cover broader areas not addressed in device-specific guidance documents. If you have questions about how this guidance and a device-specific guidance apply to a particular issue, please contact FDA to discuss. In addition, this guidance does not address review issues unique to combination products. For information on combination products, please refer to the [Office of Combination Products webpage](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018184.htm) (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/OfficeofScienceandHealthCoordination/ucm2018184.htm>).

IV. The 510(k) Decision-Making Process

A 510(k) is a premarket submission made to FDA to demonstrate that the new device to be marketed is “substantially equivalent” to a legally marketed device⁹ (21 U.S.C. §§ 360(k), 360(n), 360c(f)(1) & 360c(i); 21 CFR 807.92(a)(3)) which is not subject to PMA. Manufacturers must compare their new device to a similar legally marketed device to support its substantial equivalence (21 U.S.C. § 360c(i); 21 CFR 807.92(a)(3)).

The most commonly used method of demonstrating substantial equivalence is through the submission and FDA review and clearance of a Traditional 510(k). Under 21 CFR 807.87, FDA established basic content requirements for 510(k)s to be submitted by device manufacturers in support of substantial equivalence. The Agency has provided a general framework on how to format an original submission for a Traditional 510(k) in FDA’s Guidance for Industry and FDA Staff, “[Format for](#)

⁹ Under 21 CFR 807.92(a)(3), a legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I, or a device which has been found to be substantially equivalent through the 510(k) premarket notification process.

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(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm084365.htm>). Although the basic content requirements apply to all 510(k)s, the type of data and information necessary to establish substantial equivalence varies by the type of device and the differences between the new device and the predicate device. FDA has issued many device-specific guidance documents that clarify the data that should be included in 510(k)s for particular device types. If a manufacturer is unsure of what information to include within a 510(k) submission, the manufacturer may contact FDA and submit a pre-submission to seek additional feedback to ensure submissions contain appropriate data elements. For more information on the pre-submission process, see FDA's Guidance for Industry and FDA Staff, "[Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)" (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>).

Please note that the use of the [Standards Data Report for 510\(k\)s \(Form 3654\)](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf) (<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM081667.pdf>), recognized consensus standards, and device-specific guidance documents is not limited to Abbreviated 510(k) submissions. Appropriate reliance on these documents can facilitate the review of all 510(k) submissions and can help to make the review process more consistent. Medical device manufacturers should consider relying on and citing to standards and device-specific guidance documents wherever appropriate, regardless of the type of 510(k) submission.

A new device does not need to be identical to the predicate device for it to be found substantially equivalent to the predicate device. In FDA's experience, it is rare for a new device to be identical to a predicate device. Given the diversity of technologies evaluated under this review standard, this guidance adopts a flexible approach to determining "substantial equivalence" to accommodate evolving technology while maintaining predictability and consistency to promote confidence among device developers, practitioners, and patients.

A. The 510(k) Review Standard***1. The Statutory Standard***

The 510(k) review standard (substantial equivalence of a new device to a legally marketed (predicate) device) differs from the PMA review standard (reasonable assurance of safety and effectiveness). The 510(k) review standard is comparative, whereas the PMA standard relies on an independent demonstration of safety and effectiveness. Nonetheless, the principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review. The standard for a determination of substantial equivalence in a 510(k) review is set out in section 513(i) of the FD&C Act, which states:

Substantial Equivalence

(i)(1)(A) For purposes of determinations of substantial equivalence under subsection (f) and section 520(l), the term "substantially equivalent" or "substantial equivalence" means, with respect to a device being compared to a predicate device, that the device has the same intended use as the predicate device and that the Secretary by order has found that the device

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(i) has the same technological characteristics as the predicate device, or

(ii)(I) has different technological characteristics and the information submitted that the device is substantially equivalent to the predicate device contains information, including appropriate clinical or scientific data if deemed necessary by the Secretary or a person accredited under section 523, that demonstrates that the device is as safe and effective as a legally marketed device, and (II) does not raise different questions of safety and effectiveness than the predicate device.

(B) For purposes of subparagraph (A), the term “different technological characteristics” means, with respect to a device being compared to a predicate device, that there is a significant change in the materials, design, energy source, or other features of the device from those of the predicate device.

Safety and effectiveness factor into both parts of the FDA’s review. First, FDA must find that the intended use of the device and its predicate are “the same.” As discussed in the Intended Use Section of this guidance, differences in the indications for use, such as the population for which a device is intended or the disease a device is intended to treat do not necessarily result in a new intended use. Such differences result in a new intended use when they affect (or may affect) the safety and/or effectiveness of the new device as compared to the predicate device and the differences cannot be adequately evaluated under the comparative standard of substantial equivalence. (See **Section IV.D.**)

Second, when comparing a new device to a predicate device, FDA must find that the two devices have “the same technological characteristics,” or that a “significant change in the materials, design, energy source or other features of the device” does not raise different questions of safety and effectiveness and that the device is as safe and effective as a legally marketed device.

Although the 510(k) process involves a comparison of a new device to a predicate device rather than an independent demonstration of the new device’s safety and effectiveness, as is required for approval of a PMA, in both cases FDA’s review decision reflects a determination of the level of control necessary to provide a “reasonable assurance of safety and effectiveness.”¹⁰ The evidentiary standard, however, is different. In the 510(k) context, FDA generally relies, in part, on FDA’s prior determination that a reasonable assurance of safety and effectiveness exists for the predicate device. Demonstrating basic similarities between a new device and a predicate device typically requires manufacturers to provide descriptive information such as a comparison of specifications, materials, and technology. In contrast, FDA generally evaluates differences between the new device and the predicate device to determine their effect on safety and effectiveness. It follows that the evidence necessary to show substantial equivalence will increase as differences between the new device and the predicate device increase if those differences significantly affect, or may significantly affect, safety or effectiveness (21 CFR 807.81).

¹⁰ Under section 513(a)(2) of the FD&C Act, the safety and effectiveness of a device are to be determined:

- (A) with respect to the persons for whose use the device is represented or intended,
- (B) with respect to the conditions of use prescribed, recommended, or suggested in the labeling of the device, and
- (C) weighing any probable benefit to health from the use of the device against any probable risk of injury or illness from such use.

*Contains Nonbinding Recommendations***2. The Least Burdensome Principle**

The FDA Modernization Act of 1997 (FDAMA) added two provisions, commonly known as “the least burdensome provisions,” to the FD&C Act; these were amended by the FDA Safety and Innovation Act of 2012 (FDASIA) (Pub. L. 112-144; 126 Stat. 1051). The provision relating to substantial equivalence, section 513(i)(1)(D), states:

- (i) Whenever the Secretary requests information to demonstrate that devices with differing technological characteristics are substantially equivalent, the Secretary shall only request information that is necessary to making substantial equivalence determinations. In making such request, the Secretary shall consider the least burdensome means of demonstrating substantial equivalence and request information accordingly.
- (ii) For purposes of clause (i), the term “necessary” means the minimum required information that would support a determination of substantial equivalence between a new device and a predicate device.
- (iii) Nothing in this subparagraph shall alter the standard for determining substantial equivalence between a new device and a predicate device.

Although the statutory provision refers only to information requests related to determining the substantial equivalence of technological characteristics of a device and its predicate, the underlying principle that information requests should relate to the review standard is a basic principle of good regulatory practice with broad applicability to the 510(k) decision-making process.

FDA’s guidances, “[The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm)”

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm>) and “[Suggested Format for Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions of FDAMA](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073679.htm)”

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073679.htm>) (“the Least Burdensome Guidances”), explain how FDA intends to apply the least burdensome provisions. “The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles” interprets least burdensome as “a successful means of addressing a premarket issue that involves the most appropriate investment of time, effort, and resources on the part of industry and FDA,” and specifies that the least burdensome provisions do not affect the statutory premarket review standards for devices. The recommendations discussed in this guidance for evaluating substantial equivalence are consistent with the principles discussed in the Least Burdensome Guidances, but applies them by discussing the considerations that may affect the type of information necessary to demonstrate substantial equivalence at different decision points in the review of a 510(k).

3. Categories of NSE Determinations

The K86-3 Guidance stated: “If it is clear from an initial review that a new device has a[n] intended use or technological feature that makes it NSE, the Center will not review or require performance information in the 510(k). Instead the applicant will be notified that the device is NSE, and any performance data will be reviewed in a PMA or reclassification petition.” The same is not true for NSE decisions based on a lack of performance data, which do not preclude submission of a new 510(k) containing different or additional data to support a finding of substantial equivalence. Thus, it

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has been FDA's longstanding policy to treat NSE determinations as falling into two categories: (1) those that reflect FDA's affirmative determination that the device is a Class III device and cannot be reviewed in a 510(k) submission, and (2) those that reflect inadequacies in the evidence that preclude a finding of substantial equivalence.

The first category of NSE determinations includes a variety of different decisions, such as a finding of a lack of a predicate device, a new intended use, or different technological characteristics that raise different questions of safety or effectiveness when the new device is compared to the cited predicate device, that as a matter of law results in an NSE determination. In most cases, FDA will provide the opportunity for the manufacturer to respond to initial concerns regarding the equivalency of the new device's intended use or technology to a predicate device via response to a request for additional information. When FDA issues an NSE letter for a reason in this first category, the letter will typically not identify performance-based deficiencies. Consequently, the device is automatically classified into Class III and will require PMA approval,¹¹ or if eligible, granting of a *De Novo* before marketing. If FDA believes that the device found NSE may be eligible for the *De Novo* program, the NSE letter will typically indicate FDA's recommendation. More information regarding the *De Novo* program can be found in FDA's Guidance for Industry and CDRH Staff, "[New Section 513\(f\)\(2\) - Evaluation of Automatic Class III Designation](#)"

(<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080197.pdf>).

The second category of NSE determinations is for those devices for which FDA has not affirmed that the new device has a different intended use or that the different technological characteristics raise different questions of safety or effectiveness when compared to the cited predicate device, but rather that the information provided in the submission is insufficient to demonstrate substantial equivalence to the predicate device. In this situation, FDA generally first identifies the specific additional information – typically related to performance testing – that needs to be provided so that FDA may complete its evaluation of substantial equivalence. Upon receipt of FDA's request for additional information (either through a formal letter, email, phone call or fax), the manufacturer has the opportunity to respond to FDA's request. If the manufacturer in its response does not provide the requested information or a substantive justification for not providing the requested information, FDA will consider the response incomplete and place the submission immediately back on hold as an incomplete response. Once a complete response is received, FDA will work with the manufacturer to try to resolve identified deficiencies in an interactive capacity following the timeframes and interactions instituted with the passage of the Medical Device User Fee Amendments of 2012 (MDUFA III).¹² For more information on communications during the review of a 510(k) submission, see FDA's Guidance for Industry and FDA Staff, "[Types of Communication During the Review of Medical Device Submissions](#)"

¹¹ Alternatives to PMAs include submission of a Product Development Protocol (PDP) (Section 515(f) of the FD&C Act) or a Humanitarian Device Exemption (HDE) (Section 520(m)(2) of the FD&C Act and 21 CFR 814.104). An HDE may be an appropriate option if the device has been determined by the Office of Orphan Products Development to be eligible for an HDE through a Humanitarian Use Device (HUD) designation (21 CFR 814.100 and 814.102). Unlike other regulatory submissions, given the limited patient population, an HDE only has to demonstrate a reasonable assurance of safety and probable benefit (Section 520(m)(2) of the FD&C Act and 21 CFR 814.104). For more information on HUD designations, please see FDA's guidance "[Humanitarian Use Device \(HUD\) Designations](#)" (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM336515.pdf>).

¹² The passage of FDASIA (Pub. L. 112-144) on July 9, 2012, included the Medical Device User Fee Amendments of 2012 (MDUFA III), Title II of FDASIA (126 Stat. 1002), which reauthorized the device user fee program for another five years. The [MDUFA III Commitment Letter](#) (<http://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf>) outlines changes to the review timeframes and/or expected interactions for many premarket submissions.

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(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm341918.htm>). If the manufacturer does not respond at all to FDA's requests for additional information, the submission will be subsequently withdrawn by FDA within the timeframe specified by FDA's Guidance for Industry and FDA Staff, "[FDA and Industry Actions on Premarket Notification \(510\(k\)\) Submissions: Effect on FDA Review Clock and Goals](#)" (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089738.pdf>). If a 510(k) is withdrawn due to a lack of response, the manufacturer may submit a new 510(k) with additional information that addresses the outstanding deficiencies communicated by FDA based on the review of the prior 510(k). If the manufacturer provides the requested information after the withdrawal date, it will be considered and processed as a new 510(k) (21 CFR 807.87(l)); therefore, all information previously submitted would have to be resubmitted so that the new 510(k) is complete. If a new 510(k) is submitted to address deficiencies raised in this type of NSE letter, as explained in FDA's Guidance for Industry and FDA Staff, "[Refuse to Accept Policy for 510\(k\)s](#)" (<http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm315014.pdf>), the new 510(k) should clearly identify how the outstanding issues have been addressed and cross-reference where the new information is provided within the newly submitted 510(k). Failure to cite the prior 510(k) number may result in a Refuse to Accept decision.

B. The Flowchart

The 510(k) Substantial Equivalence Decision-Making Process Flowchart (K86-3 Flowchart) was originally presented in the K86-3 Guidance and has served as the overarching "framework" for 510(k) decision-making for decades. The K86-3 Flowchart has provided a concise summary of the 510(k) decision-making process and serves as a common frame of reference for scientific and regulatory discussions related to the 510(k) process. However, the K86-3 Flowchart has not been updated since 1986 and, consequently, does not incorporate certain terminology set out in subsequent amendments to the FD&C Act. Furthermore, the K86-3 Flowchart's visual structure may be more complex than necessary. To specifically address these issues, a modified Flowchart is provided that both more closely tracks the language of section 513(i) of the FD&C Act and relevant regulations, and visually simplifies our presentation of the decision-making algorithm.

It should be noted that the 510(k) Decision-Making Flowchart (the Flowchart) (see **Appendix A**) is meant to be used in conjunction with this guidance document and not as a "stand-alone" document without appropriate references to the context of each critical decision point.

C. Predicate Device(s)

As discussed in Section IV.A, the 510(k) review standard is substantial equivalence of a new device to a legally marketed device. Under 21 CFR 807.92(a)(3), a legally marketed device is a device that (i) was legally marketed prior to May 28, 1976 (preamendments device¹³) and for which a PMA is not required; *or* (ii) has been reclassified from Class III to Class II or I; *or* (iii) has been found SE through the 510(k) process. For purposes of determining substantial equivalence, the legally marketed device is commonly referred to as the "predicate device" or "predicate." While manufacturers may identify more than one predicate device, only one is required. FDA encourages

¹³ See [Preamendment Status](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/ComplianceActivities/ucm072746.htm>).

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manufacturers to identify a single predicate device to simplify and facilitate the decision-making process. When a manufacturer does identify **multiple predicates**, the **primary predicate** refers to the one with indications for use and technological characteristics most similar to the device under review. Although using a single predicate is optimal, when multiple predicates are appropriate (as described in the examples below), FDA recommends identifying a primary predicate in the submission to facilitate a timely, well-supported decision.

Section 513(i) of the FD&C Act and 21 CFR 807.100(b) state that, for a new device to be considered substantially equivalent to a predicate device, the new device must have the same intended use as the predicate device **and** the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness than the predicate device. Therefore, the use of a “split predicate” is inconsistent with the 510(k) regulatory standard. “Split predicate” refers to a situation in which a manufacturer is attempting to “split” the 510(k) decision making process by demonstrating that a new device has the same intended use as one marketed device while comparing the new device’s technological characteristics with a second marketed device that has a different intended use. As a general matter, to find a device substantially equivalent, FDA must be able to address Decision Points 1 through 4 in the Flowchart using one predicate device identified by the manufacturer. FDA may use one or more additional devices proposed by the manufacturer in certain instances to help support substantial equivalence, as described below.

1. Multiple Predicates

A manufacturer may use multiple predicate devices¹⁴ to help demonstrate substantial equivalence in certain circumstances. Manufacturers sometimes choose to do this when combining features from two or more predicate devices with the same intended use into a single new device, when seeking to market a device with more than one intended use, or when seeking more than one indication for use under the same intended use, as described in the examples below.

Multiple Predicates Example 1:

A manufacturer submits a 510(k) for a new hemodialysis catheter. This new catheter has an extension (the portion of the device outside the body) design that is similar to predicate A and a tip (the portion of the device inside the body) design similar to predicate B. Both predicates A and B have the same intended use as the new device. In this example, the manufacturer is relying on both predicate A and predicate B, which have the same intended use as the new device, to support substantial equivalence with respect to technological characteristics. The manufacturer may choose either predicate as the primary predicate in this example.

Multiple Predicates Example 2:

A manufacturer submits a 510(k) for a plate indicated for fixation of both diaphyseal (the shaft of a long bone) and epiphyseal (the ends of a long bone) fractures, i.e., the plate can be used to set a long bone, such as the femur or thigh bone, that is broken in the middle or at the ends. The manufacturer cites a predicate device that is a plate indicated for middle bone fractures only and another predicate device that is indicated specifically for bone tip fractures. While the indications for use of each predicate device are different, both devices have the *same* intended use, namely,

¹⁴ See [510\(k\) and Science Report Recommendations: Summary and Overview of Comments and Next Steps](http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf). (<http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf>).

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fracture fixation of the long bone.¹⁵ Thus, although the manufacturer could have used a single predicate device, in cases where a manufacturer intends to market a device for more than one indication and a different predicate exists to support each specific indication, the manufacturer may cite more than one relevant predicate device to support an SE determination. In this case, using two appropriate predicates clearly identified by the manufacturer helped to facilitate clearance of the new device, which was indicated to treat both types of fractures treated by the predicates.

Multiple Predicates Example 3:

A manufacturer submits a 510(k) for a laser platform that consists of two hand pieces: an Er:YAG laser hand piece and a Q-Switch Nd:YAG laser hand piece. The manufacturer cites two predicates to support substantial equivalence for both of their requested proposed indications for use. In this case, each predicate cited does not share the same indications for use as the other predicate because each predicate consists of only one hand piece in which the indications correspond to the indications for one of the hand pieces included in the new device. However, the indications for both hand pieces fall within the scope of the general intended use of lasers, “incision, excision, ablation, vaporization of soft tissue.” The Er:YAG laser hand piece is indicated for the incision, excision, ablation, vaporization of soft tissue; and the Q-Switch Nd:YAG laser hand piece is indicated for tattoo removal. The new device is found substantially equivalent to the predicate devices because it has the same intended use and the new device’s technological characteristics are similar to the cited predicates.

In each example above, a single predicate could have been used to establish substantial equivalence of the new device, but the manufacturer used multiple predicates to show that FDA had found similar technology or indications to be substantially equivalent.

Multiple Predicates Example 4:

A manufacturer submits a 510(k) for a multi-parameter monitor. The monitor includes different technologies that can stand alone independently, but can also be used together for the general intended use of measuring patient vital information. If there is a predicate device for each of the parameters, then the combination of these parameters, assuming that monitoring of each individual parameter does not interfere with the others, can be found substantially equivalent.

It should be noted that in Examples 2, 3, and 4 above, the specific indications of the new device may necessitate new performance testing, but they do not change the overall intended use of the device relative to the predicates. These types of situations will need to be assessed on a case-by-case basis; in some situations, a specific indication may actually alter the overall intended use of the device in which case the multiple predicates concept may not be applicable. More information regarding when a specific indication is reasonably included within a general indication can be found in FDA’s Guidance for Industry, “[General/Specific Intended Use](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm>).

Features can also be added to a new device to increase convenience of use and/or functionality, without altering the intended use or risk profile (relative to a predicate) of the new device. Under

¹⁵ It is important to note that if multiple predicates are used to support the same intended use, any different technological characteristics between the new device and the cited predicate devices must not raise different questions of safety and effectiveness. Section 513(i) of the FD&C Act (21 U.S.C. § 360c(i)).

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such circumstances, the device with the added feature can be reviewed in a 510(k), even if the added feature consists of a component that may fall under a different classification regulation. A catheter-thermometer construct is useful in illustrating this concept.

Multiple Predicates Example 5:

A manufacturer submits a 510(k) for a urinary catheter with a thermometer. The thermometer/temperature-measuring feature is not affecting the intended use or risks of using the catheter (assuming it is integrated appropriately), nor is the catheter affecting the performance or risk profile of the thermometer. The temperature-measuring feature is a convenience component that is added to the catheter, with the intended use of the device still being that of the catheter to pass fluids to or from the urinary tract, so it is appropriate to have a legally marketed catheter serving as the primary predicate.

There are obvious limitations to feature/component additions in the 510(k) program. If a feature is added which alters the intended use of the new device and/or alters the safety profile (i.e., introduces new or additional risk factors) such that comparison to a predicate cannot be made, the new device is ineligible for the 510(k) program. A new device with a new design feature or added component must meet the SE standard with at least a single predicate from the same classification regulation.

2. *Reference Devices*

When demonstrating substantial equivalence in a 510(k) submission, manufacturers sometimes direct attention to similar situations FDA has encountered in the past. If a manufacturer successfully navigates through Decision Point 4 on the Flowchart using a single predicate device, other legally marketed devices, which FDA calls “**reference devices**,” may be used to support scientific methodology or standard reference values at Decision Point 5a.

It is important to note that a reference device is not considered a predicate device and it cannot be used to address Decision Points 1 – 4 on the Flowchart. Additionally, the applicability of a reference device will need to be reviewed by FDA for its appropriateness. If a selected reference device is used in an anatomical location or for a physiological purpose that is considerably different than that of the new device, its utility as a reference device may be limited.

If a manufacturer intends to use a reference device, the manufacturer should provide a scientific rationale that justifies its use. This concept is illustrated in the Reference Device Examples below. We recommend that you read these examples side-by-side with the Flowchart in Appendix A so that you can follow the decision-making process.

Reference Device Example 1: A manufacturer submits a 510(k) for a total knee implant with coating X (the new device). Other coated knee implants with the same intended use with coatings A, B, and C are legally marketed. In addition, a total hip implant with coating X is legally marketed. The manufacturer cites the legally marketed knee implant with coating A as the predicate device. FDA determines that the new device has an appropriate predicate device (thus, answering “yes” at Decision Point 1) and the new device has the same intended use as the predicate device (thus, answering “yes” at Decision Point 2 in the Flowchart).¹⁶ However, FDA

¹⁶ The answer at Decision Point 2 may possibly be “no” if the predicate device is uncoated. Introducing a coated arthroplasty device into an anatomical location which previously only had non-coated devices would likely create a new intended use due to the different fixation methods.

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determines that the new device does not have the same technological characteristics as the predicate device (thus, answering “no” at Decision Point 3 in the Flowchart), because the new device (knee implant with coating X) has a chemical profile different from the chemical profile of the cited predicate device (knee implant with coating A). There are no other technological differences between the new device and the cited predicate device (knee implant with coating A). FDA determines that the new device does not raise different questions of safety and effectiveness. In this case, FDA determines that the safety and effectiveness questions regarding the coating material are whether it is biocompatible and whether it affects the fixation of the implant and these questions apply to both the new device and predicate device (thus, answering “no” at Decision Point 4 in the Flowchart).

After Decision Point 4 in the Flowchart, if appropriate, the manufacturer may refer to the reference device (the hip implant with coating X in this situation) to support the appropriate scientific methods for the characterization of coating X on the new knee implant device. In this particular example, the manufacturer provided an adequate scientific rationale to support that the methods used to characterize the biocompatibility and characteristics of the coating (e.g., strength, abrasion, etc.) on the hip implant are applicable to the knee implant.¹⁷ The reference device (hip implant with coating X) is used in this case solely to assist with the characterization of the coating on the new device (knee implant with coating X).

Reference Device Example 2: A manufacturer submits a 510(k) for an over-the-counter blood glucose test system (glucose meter). Other glucose meters with the same intended use are legally marketed. The manufacturer cites a legally marketed glucose meter as the predicate device. FDA determines that the new device has an appropriate predicate device (thus, answering “yes” at Decision Point 1) and the new device has the same intended use as the predicate device (thus, answering “yes” at Decision Point 2 in the Flowchart). The manufacturer has not demonstrated that the new device has the same technological characteristics as the predicate device (thus, answering “no” at Decision Point 3 in the Flowchart), but the new device does not raise different questions of safety and effectiveness (thus, answering “no” at Decision Point 4 in the Flowchart).

Because glucose meters of this type typically have relatively high inherent total error due to limitations in their technology and other factors, in order to sufficiently characterize the analytical performance of the new device (and answer “yes” at Decision Point 5a in the Flowchart), the new device uses the same approach to characterize analytical performance as the predicate device. Specifically, the accuracy of the new device is evaluated by comparing its blood glucose results to reference values generated on a laboratory-based glucose measurement device that has been well-validated for precision and accuracy, and that is traceable to a higher order, e.g., internationally recognized standard. If the performance of the new device (including accuracy compared to the reference values from a reference device) is equivalent to the performance of the predicate device (including accuracy of the predicate compared to the reference values from a reference device), the FDA would determine that the data demonstrate equivalence (thus answering “yes” at Decision Point 5b in the Flowchart).

¹⁷ The applicability of the scientific methodology used to characterize certain aspects of a legally marketed device will depend upon the specific scenario. In this example, it is determined that the duration of contact, which affects the biocompatibility testing, and the mechanical testing conducted to fully characterize the coating on the hip implant are directly relevant and informative for the same coating applied to the knee implant. However, if the manufacturer wanted to rely on the scientific methodology for a coating used in a different type of implant (e.g., cardiovascular), it may not be appropriate to exercise this approach.

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3. *Lack of Predicate Device*

If a predicate device with the same intended use cannot be identified, or if the new device's different technological characteristics raise different questions of safety or effectiveness, a manufacturer may submit a *De Novo* request, either after receipt of an NSE letter or directly requesting classification through the *De Novo* process.¹⁸ For high risk devices, a PMA (or alternative submission type) may be required.

4. *Identification and Documentation of the Predicate(s)*

Although manufacturers may cite more than one predicate device in a 510(k), FDA recommends that the manufacturer clearly identify the primary predicate device to which substantial equivalence is being claimed.¹⁹ Further, as part of the decision-making process, FDA should clearly cite the predicate device relied upon in determining substantial equivalence for the new device in its review documentation. If multiple predicates or reference devices are used in accordance with this guidance, the manufacturer should identify each device and explain why more than one predicate or a reference device is necessary and appropriate to support substantial equivalence. Manufacturers should choose the most appropriate single or primary predicate for their new device, and should limit the multiple predicates to those most helpful in facilitating review of the new device and to the minimum number necessary to support substantial equivalence. Predicate device(s) relied upon for SE must be accurately cited in the 510(k) Summary (see **Appendix B**) according to 21 CFR 807.92 (a)(3). Reference devices also may be cited in the 510(k) Summary.

D. Intended Use

Under section 513(i) of the FD&C Act, FDA may only determine that a device is substantially equivalent to a predicate device if it has the same intended use.²⁰ (Refer to the 510(k) Decision-Making Flowchart in **Appendix A**). A finding of NSE due to a new intended use is relatively rare. Approximately 10% of all NSE decisions are due to a new intended use.²¹ This type of NSE determination generally reflects a finding that a change in the *indications for use* of a device creates a

¹⁸ Section 607 of FDASIA (Pub. L. 112-144; 126 Stat. 1054), which was enacted on July 9, 2012, amended section 513(f)(2) of the FD&C Act by providing the option of directly submitting a request for *De Novo* classification without the need for an NSE determination. A manufacturer who intends to submit a direct *De Novo* request is encouraged to engage in dialogue with FDA through the pre-submission process to obtain additional feedback related to whether a valid predicate exists for the new device and appropriate performance data that will be necessary to support a reasonable assurance of safety and effectiveness. For more information on the pre-submission process, see FDA's Guidance for Industry and FDA Staff, "[Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf)" (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM311176.pdf>).

¹⁹ Although devices recently cleared under the 510(k) program are often selected as the predicate device to which substantial equivalence is claimed, any legally marketed Class II or Class I device may be used as a predicate device. However, section 513(i)(2) of the FD&C Act provides that a predicate device may not have been removed from the market at the initiative of the Commissioner of Food and Drugs or been determined to be misbranded or adulterated by a judicial order. *See also* 21 CFR 807.100.

²⁰ This guidance is not intended to supplant either of the following guidance documents: "[Determination of Intended Use for 510\(k\) Devices: Guidance for CDRH Staff](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm) (Update to K98-1)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm>) or "[General/Specific Intended Use](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm>).

²¹ Refer to "[Initial Results of 510\(k\) Audit: Analysis of Not Substantially Equivalent \(NSE\) Determinations](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm259173.htm)" (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm259173.htm>).

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new *intended use*. This section of the guidance provides further clarification about the terms “intended use” and “indications for use,” describes how FDA determines what the intended use of a device is, and provides examples of changes in indications for use that may constitute a new intended use making the device ineligible for review under the 510(k) program.

1. Explanation of Intended Use and Indications for Use

For purposes of substantial equivalence, the term **intended use** means the general purpose of the device or its function, and encompasses the indications for use. The term **indications for use**, as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.²² The intended use of a device is one criterion that determines whether a device can be cleared for marketing through the 510(k) process or must be evaluated in a PMA (or alternative submission type), or if appropriate, a *De Novo* request. The proposed labeling in a 510(k) is used to determine a device’s intended use (Section 513(i)(1)(E) of the FD&C Act). The indications for use statement in a 510(k) is also a factor in determining a device’s intended use. Consistency between the indications for use statement and the proposed labeling will facilitate the review of the 510(k).

A finding of substantial equivalence means that the indications for use of the new device fall within the intended use of the predicate device and, therefore, the two devices have the same intended use. For devices with general indications for use that do not specify a disease, condition, or population (or an anatomical site from which a disease state or population may be inferred), the indications for use and intended use are the same. Such indications for use are referred to as “tool type” indications for use. Examples of devices with “tool type” indications for use include devices such as scalpels, which are often indicated for cutting tissue, or imaging devices, which are often indicated for taking images of the body. A scalpel indicated for removing a particular type of cancerous cell, however, has indications for use specific to the identified disease, condition, or population, and therefore, does not have “tool type” indications for use.

2. Determining Intended Use

Section 513(i)(1)(E)(i) of the FD&C Act provides that the FDA’s determination of intended use of a device “shall be based upon the proposed labeling” submitted in a 510(k). When a review of the indications for use and all other information in the proposed labeling submitted with a 510(k) supports an intended use that is the same as that of the predicate device, FDA will determine that the new device and predicate device have the same intended use. This guidance does not address FDA’s authority to consider information outside the labeling in reviewing a 510(k) and issue an “SE with limitations” under section 513(i)(1)(E) of the FD&C Act because “there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling” and such use “could cause harm.” For information on “SE with limitations,” please see the guidance document, “[Determination of Intended Use for 510\(k\) Devices; Guidance for CDRH Staff \(Update to K98-1\)](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm082162.htm>). When a review of the labeling submitted with a 510(k) shows that the indications for use of a new device and predicate device differ, FDA must evaluate whether the new²³ indications for use

²² We have a long-standing policy of applying the definition of indications for use in the PMA regulation at 21 CFR 814.20(b)(3)(i) in the same way in the 510(k) context.

²³ For purposes of Section IV.D, the term “new” in describing indications for use refers to an indication that is new or differs from that of the predicate device.

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fall within the same intended use as that of the predicate device. As described in Section IV.A, because the substantial equivalence determination is grounded in safety and effectiveness, this determination depends upon the safety and effectiveness of the new device for the new indications relative to the safety and effectiveness of the predicate device.

Once FDA has determined the indications for use of the new device upon review of the proposed labeling, FDA may rely upon relevant clinical and/or scientific information, that does not appear in the proposed labeling submitted with the 510(k), regarding the safety and effectiveness of the new indications for use. For example, FDA may rely upon publicly-available scientific information or Agency knowledge about how a disease progresses to determine whether indications for use to treat a certain disease or anatomical site constitute a new intended use.

3. *Determining When Indications for Use Result in a New Intended Use*

Not every change in indications for use that may affect safety or effectiveness will result in a finding of a new intended use. Only a change in the indications for use that raises different questions of safety and effectiveness and therefore, precludes a meaningful comparison with the predicate device constitutes a new intended use. FDA may find changes in indications for use of a device to constitute a new intended use when the changes raise a safety or effectiveness issue that was not raised by the predicate device, or the changes have the potential to significantly increase a safety or effectiveness concern raised by the predicate device.²⁴ In the first case, reliance on a predicate device is inadequate because the safety or effectiveness issue was not considered in reviewing the 510(k) for the predicate device. In the second case, although the safety or effectiveness issue may have been considered in the 510(k) for the predicate device, the finding of substantial equivalence for the predicate device cannot be generalized to the new indications for use because of a probable, significant change in the incidence or severity of the issue. In both cases, the predicate device is not an adequate “proxy” for an independent determination of safety and effectiveness.

Illustrative Example 1: A new device’s instructions for use describe using a general surgery device in a body cavity, but the predicate device is used only to treat external injuries. A comparison to the predicate device may not be adequate to address the risk of infection posed by internal use of the device. Because of the need for an independent assessment of an issue that was not evaluated or was of significantly less concern during FDA’s review of the 510(k) for the predicate device, FDA may determine that the indication for use of the new device constitutes a new intended use and a PMA (or alternative submission type), or if appropriate, a *De Novo* request, is required.

Illustrative Example 2: A 510(k) for an existing surgical ablation device cleared for ablation of cardiac tissue has now been submitted for the treatment of atrial fibrillation. While the devices are similar in technology, additional clinical testing has been conducted to demonstrate that not only can the device ablate cardiac tissue, but also that doing so can treat atrial fibrillation safely and effectively. While the question of whether or not cardiac tissue can be safely and effectively ablated was raised by the predicate device, FDA has determined that the specific indication for the treatment of atrial fibrillation constitutes a new intended use because it raises questions of both safety and effectiveness not raised by the predicate device. Specifically, treatment of atrial

²⁴ See 21 CFR 807.92(a)(5); see also FDA guidance “[General/Specific Intended Use](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073944.htm>) which implements section 513(i)(1)(F) of the FD&C Act.

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fibrillation requires extensive ablation to create linear lines of conduction block in a maze-like pattern that eliminates fibrillatory conduction in the atria. The effectiveness assessment for the treatment of atrial fibrillation warrants a clinical outcome study. Furthermore, the risks of iatrogenic heart block and collateral cardiac or extra-cardiac damage are either raised or increased when such a complex and extensive lesion set is created. As a result, a PMA (or alternative submission type) is required.

4. Changes in Indications for Use that May Result in a New Intended Use

All new indications for use should be evaluated to determine whether they reflect a new intended use. Certain types of changes, however, warrant particular attention in evaluating whether the new indications for use result in a new intended use because they are more likely to significantly affect safety or effectiveness:

- a change from a functional/performance indication to a treatment or aesthetic indication;
- a change from a diagnostic indication to a screening indication, or vice versa;
- a change in the anatomical structure of use;
- a change in the patient population (e.g., adult versus pediatric; different disease populations);
- a change in the clinical context or setting (e.g., periodic monitoring versus continuous monitoring; hospital versus home use).

E. Technological Characteristics

After FDA has determined that a valid predicate device exists for a new device and that both devices have the same intended use, FDA will move to Decision Points 3 and 4 of the Flowchart (see **Appendix A**). In these steps of the 510(k) review process, FDA compares the technological characteristics of the new device and the predicate device to determine whether the new device has the same technological characteristics as the predicate, and if not, whether the different technological characteristics raise different questions of safety and effectiveness.²⁵ Devices reviewed under the 510(k) program commonly have different technological characteristics from their predicate device(s); however, FDA rarely makes a finding of NSE at Decision Point 4.²⁶

1. Step 1 – Identification of Technological Characteristics of the New and Predicate Device

For FDA to evaluate whether differences exist between the technological characteristics of the new device and the predicate device(s), the manufacturer should clearly identify the technological characteristics of each device individually. Technological characteristics include materials, design,

²⁵ Section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.100(b)(2). “Different technological characteristics” are defined as “significant change in the materials, design, energy source, or other features of the device from those of the predicate device.” Section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A).

²⁶ Refer to “[Initial Results of 510\(k\) Audit: Analysis of Not Substantially Equivalent \(NSE\) Determinations](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm259173.htm)” (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm259173.htm>).

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energy source, and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2)(ii)(A).

To facilitate FDA's review of a device's technological characteristics, the device description in a 510(k)²⁷ should include the information necessary to explain the new device's technological characteristics, including similarities in materials, design, energy source, and other device features. This information will be evaluated by FDA to determine whether the technological characteristics of the new device are different and, if so, whether they raise different questions of safety and effectiveness as compared to the predicate(s). Examples of key characteristics that should be provided as part of a 510(k) submission include, but are not limited to, the following features:

- An overall description of the device design. A complete description of the device may be facilitated by the submission of engineering drawings or other figures. If the device consists of multiple components, a diagram identifying how the different components of the device system work together may be beneficial. The device description should also include a discussion of the physical specifications, dimensions and design tolerances that are critical to the new device.²⁸ Significant features of the new device should have a clear purpose within the context of the overall design and intended use. In cases where this is not apparent, it is important for the 510(k) submission to provide a discussion of how a particular device design or component contributes to the overall use and function of the new device.
- Materials. For many devices, a complete identification of the detailed chemical formulation used in the materials of construction, especially for those materials that come into contact with the patient, should be provided. Note that the FDA does not clear/approve materials.²⁹ Any additives, including color additives, coatings, or other surface modifications should also be identified. For some devices, the processing of the material (e.g., forged vs. cast) or the state of the material (e.g., amorphous vs. crystalline) may also significantly contribute to or affect the overall safety or function of the device, and so should be included as part of the device description, as applicable.
- Energy sources. This not only includes energy delivery to the device, including the use of batteries, but also energy delivery that is part of the functional aspect of the device (e.g., laser, radiofrequency, ultrasound, etc.) and that affects the patient and/or the health care

²⁷ FDA's regulations require manufacturers to include in their 510(k)s "[a] description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties." 21 CFR 807.92(a)(4); *see also* 21 CFR 807.87(f).

²⁸ The original Flowchart from the K86-3 Guidance included a decision point related to whether or not "descriptive characteristics" were precise enough to ensure equivalence. However, the term "descriptive characteristics" does not appear in the statute or regulations. The 510(k) Decision-Making Flowchart described in **Appendix A** specifically addresses this to reflect the statute more closely and minimize confusion.

²⁹ For additional considerations, refer to the FDA guidance, "[Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm)" (Replaces #G87-1 #8294) (blue book memo)" (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080735.htm>). *See also* Draft Guidance for Industry and FDA Staff, "[Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing'](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf)" (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM348890.pdf>). FDA's draft guidance represents the Agency's proposed approach on this topic.

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professional using the device. Where applicable, a discussion of this characteristic should be provided.

- Other key technological features. These include, but are not limited to, software/hardware features, density, porosity, degradation characteristics, nature of reagents (recombinant, plasma derived, etc.), principle of the assay method, etc., that are not explicitly included as part of the materials, design or energy source characteristics. These technological features should be included as part of the device description in the 510(k) submission, as appropriate for the specific device technology.³⁰

A 510(k) submission must also contain information about the technological characteristics of the predicate device (21 CFR 807.87(f), 807.92(a)(3) and (a)(6)). The manufacturer of the new device should provide information necessary and sufficient to fully and clearly identify and describe the technological characteristics of the predicate device so that FDA can conduct a comparative assessment of the technological characteristics, as further described in Step 2.

2. Step 2 – Identification of Differences in Technological Characteristics Between the New and Predicate Device

Once the technological characteristics of the new and predicate device(s) have been clearly identified, the next step involves a comparison of these characteristics to identify any differences. This may involve a comparison of detailed specifications as well as a comparison of the system-level technological characteristics of the devices. FDA relies upon information provided about the predicate device, in addition to the information in our files as appropriate, and the new device to determine whether the new device has different technological characteristics (Decision Point 3) in comparison to the predicate(s).

At this point, FDA will assess whether the similarities/differences in technological characteristics between the new and predicate device(s) have been appropriately identified. FDA highly recommends that the manufacturer summarize this information in tabular format to facilitate this step of review.

3. Step 3 – Determination of Whether the Differences in Technological Characteristics Raise Different Questions of Safety and Effectiveness

If FDA determines that there are differences in the technological characteristics of the new device and the predicate device, FDA will review and evaluate all relevant information bearing on any such differences in technological characteristics to determine whether they raise different questions of safety and effectiveness for the new device as compared to the predicate device (Decision Point 4 on the Flowchart). A “different question of safety or effectiveness” is a question raised by the technological characteristics of the new device that was not applicable to the predicate device, and poses a significant safety or effectiveness concern for the new device.

Some examples are provided below to illustrate cases where the response to this general question was “yes,” i.e., the new device was determined to raise different safety and effectiveness questions in comparison to the predicate device, and the new device was found NSE.

³⁰ We encourage manufacturers to determine whether there is an applicable device-specific guidance or special controls for the device type as provided in a special controls document or classification regulation.

*Contains Nonbinding Recommendations***Illustrative Example 1**

Predicate: A biological indicator utilizing natural bacterial spores with recognized resistance characteristics as organisms for the biological indicator, where the presence of a color change or fluorescent signal is indicative of bacterial viability.

New Device: A biological indicator based on recombinant technology/genetic engineering, where the fluorescent signal is not indicative of bacterial viability; it is indicative of plasmid enzyme expression.

Intended Use: Same

Different questions of safety and effectiveness? Yes

Why: Due to the engineering of a plasmid into the biological indicator, it is possible to have viable bacteria that do not contain the plasmid in sufficient amounts to generate a signal. In this case, the biological indicator could falsely indicate that the monitored load was sterilized properly due to the absence of fluorescent signal, while there are viable non-expressing bacteria in the indicator (development of false negatives). This technological difference raises different types of safety and effectiveness concerns for using a recombinant-DNA plasmid that codes for antibiotic resistance and a signaling enzyme in the spores of a biological indicator. Appropriate test methodologies and risk assessments need to be determined to address the properties of the introduced plasmid and host bacterial spore that could affect indicator performance. Because these types of questions were not necessary to take into account for the predicate device, the new device would be found NSE.

Illustrative Example 2

Predicate: A mechanical device used for embryo dissection

New Device: An electrical device used for embryo dissection

Intended Use: Same

Different questions of safety and effectiveness? Yes

Why: In this example, changing the process from a mechanical process to an electrical energy source (e.g., laser) changes the way the device operates and raises different safety concerns regarding how the heating aspect of the electrical mechanism affects the embryo. Because these types of questions were not necessary to take into account for the predicate device, the new device would be found NSE.

Illustrative Example 3

Predicate: A device inserted into the patient's pharynx through the mouth to provide a patent airway by mechanically moving the soft tissue.

New Device: A device placed externally on the mandible and neck to apply a vacuum to move the soft tissue forward and thus "open" the airway.

Intended Use: Same

Different questions of safety and effectiveness? Yes

Why: The predicate device is invasive and placed midline in the oropharynx and does not exert pressure on the vascular, respiratory, or nerve structures in the neck, whereas the new device exerts continuous external negative pressure on these areas, raising different types of safety questions, such as the risks and potential adverse events associated with the stimulation of the nerve structures in the neck. Because these types of questions were not necessary to take into account for the predicate device, the new device would be found NSE.

In the event the answer to Decision Point 4 is "No" and the differences between the new device and the predicate device do not raise different questions of safety and effectiveness, then the scientific

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review of the performance data will proceed. However, if the answer to Decision Point 4 is “Yes” and the differences between the new device and predicate device raise different questions of safety and effectiveness, then the new device will be found NSE. Upon receipt of this type of NSE letter, the manufacturer may submit a PMA (or alternative submission type), or if appropriate, a *De Novo* request.

F. Requests for Performance Data

Although FDA may rely upon descriptive information alone to address the critical questions in the Flowchart (Decision Points 1 through 4), performance data are typically needed in a Traditional 510(k) to demonstrate the substantial equivalence of a new device to a predicate device. In addition, information on device performance described in labeling or other sections of the 510(k) should be supported with appropriate performance data. The type and quantity of performance data necessary to support a determination of substantial equivalence depend upon the device and/or device type.³¹ Performance data may be needed to address a variety of safety and effectiveness issues and may be generated from different types of tests and studies.

FDA’s data requests typically follow a stepwise analytical process to ensure the information requested reflects the least burdensome approach to establishing substantial equivalence.³² First, FDA considers whether descriptive information about the technological characteristics, such as the materials, design, and specifications, of the new device is sufficient. Very few 510(k) submissions rely solely on descriptive information about materials, design, specifications, and other technological characteristics (see 21 CFR 807.87(f) and (g)). When this information is not sufficient to support a substantial equivalence determination, FDA then considers whether non-clinical bench performance testing or analytical studies using clinical samples would be sufficient. For *in vitro* diagnostic devices (IVDs), analytical studies include, but are not limited to, evaluations of accuracy, precision, specificity, and sensitivity. Non-clinical bench performance testing includes a wide variety of test modalities that will be dependent upon the specifics of the actual device, including, but not limited to:

- mechanical, electrical, and biological engineering performance, such as fatigue, wear, tensile strength, compression, flowrate, burst pressure;
- electromagnetic compatibility (EMC);
- sterility;
- stability/shelf life;
- software validation;
- other forms of non-clinical, including device-specific.

Non-clinical animal and/or biocompatibility studies are typically requested when other forms of non-clinical bench performance testing are not sufficient to demonstrate substantial equivalence. Non-clinical laboratory studies that support the safety of medical devices must be conducted in compliance with 21 CFR Part 58, Good Laboratory Practice (GLP) for Nonclinical Laboratory

³¹ Manufacturers should also determine whether there is an applicable device-specific guidance or special controls for the device type as provided in a special controls document or classification regulation.

³² FDA follows the “least burdensome” provisions. See Final Guidance for FDA and Industry, “[The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concept and Principles](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm)” (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm085994.htm>).

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Studies, as applicable, to ensure the quality, reliability, and integrity of study data.³³ For more information on this topic, see FDA's Draft Guidance for Industry and Food and Drug Administration Staff, "[The Applicability of Good Laboratory Practice in Premarket Device Submissions: Questions & Answers](#)"

(<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm366338.htm>). FDA's draft guidance represents FDA's proposed approach on this topic.

When analytical or non-clinical bench performance testing data, or non-clinical animal and/or biocompatibility studies are insufficient, or available scientific methods are not acceptable, e.g., the scientific methods are deemed unacceptable because they are not clinically validated or are not supported by a valid scientific rationale, FDA may request clinical performance data to support a substantial equivalence determination. For 510(k)s reviewed in the Office of Device Evaluation, FDA currently requests clinical data for less than 10 percent of the 510(k) submissions. In some instances, clinical data may be a less burdensome means of demonstrating substantial equivalence than other means of performance testing, and 510(k)s reviewed in CBER for products intended to ensure the safety and effectiveness of blood and blood products typically include clinical data. Clinical data provided in support of any marketing application, including a 510(k) when those data are relevant to a substantial equivalence determination, should constitute valid scientific evidence as defined in 21 CFR 860.7(c)(2)³⁴ and must comply with the Investigational Device Exemptions (IDE) regulations as applicable.³⁵

Although not an exhaustive list of instances in which FDA may request clinical data to demonstrate substantial equivalence,³⁶ the following scenarios illustrate the most common situations in which clinical data may be requested. As explained in the Scope Section (see **Section III**), the information in this guidance and the examples below do not take the place of any device-specific guidance.

³³ The applicability of GLPs to non-clinical studies in a 510(k) submission is also mentioned in FDA's Guidance "[Refuse to Accept Policy for 510\(k\)s](#)" in the Performance Data – General section of the checklist (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm315014.pdf>).

³⁴ 21 CFR 860.7(c)(2): Valid scientific evidence is evidence from well-controlled investigations, partially controlled studies, studies and objective trials without matched controls, well-documented case histories conducted by qualified experts, and reports of significant human experience with a marketed device, from which it can fairly and responsibly be concluded by qualified experts that there is reasonable assurance of the safety and effectiveness of a device under its conditions of use. The evidence required may vary according to the characteristics of the device, its conditions of use, the existence and adequacy of warnings and other restrictions, and the extent of experience with its use. Isolated case reports, random experience, reports lacking sufficient details to permit scientific evaluation, and unsubstantiated opinions are not regarded as valid scientific evidence to show safety or effectiveness. Such information may be considered, however, in identifying a device the safety and effectiveness of which is questionable.

³⁵ In the U.S., clinical studies/investigations (*see* 21 CFR 812.3(h)) involving one or more human subjects to determine the safety or effectiveness of a device must be conducted in accordance with the Investigational Device Exemptions (IDE) regulations, 21 CFR Part 812, as applicable. In addition, such studies/investigations must comply with the regulations governing institutional review boards (21 CFR Part 56), informed consent (21 CFR Part 50), and financial disclosure (21 CFR Part 54). *See also* Guidance for Clinical Investigators, Industry, and FDA Staff, "[Financial Disclosure by Clinical Investigators](#)" (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM341008.pdf>). Studies conducted outside the U.S. generally do not have to comply with the IDE regulations, but FDA recommends that such studies be conducted in accordance with good clinical practice. For information on good clinical practice, *see* 78 FR 12664 (Feb. 25, 2013).

³⁶ The acceptability or level of data necessary to support an SE determination is product specific and therefore, not discussed in this guidance. Manufacturers should determine whether there is an applicable device-specific guidance or special controls for the device type as provided in a special controls document or classification regulation as these sources may provide further information about performance data that may be necessary in a 510(k) submission.

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Note: The examples provided below distinguish between examples that are only applicable to diagnostic devices, including IVDs, and therapeutic devices. This is because there are significant differences in the clinical data requirements for these two categories of devices.

1. New or Modified Indications for Use – Same Intended Use

In rare instances, FDA may rely upon clinical data to determine that new or modified indications for use fall within the same intended use as a predicate device.

Illustrative Examples:

- The new device is an IVD that is indicated for over-the-counter use, whereas the predicate device is indicated for prescription use in the home or prescription use in a clinical setting. The newly indicated test population might fall within the intended use of the predicate device. Clinical data (demonstrating that the user can collect the sample, generate an accurate result, and adequately interpret the result) might establish that the indication for use for the new device falls within the intended use of the predicate device.
- The new IVD is indicated for use with patients who have symptoms and signs of illness from any member of a specified set of closely related diseases. The indications for use for the predicate IVD do not include one of the diseases addressed by the new IVD. Clinical data (concerning all diseases in the newly specified set) might establish that the indications for use for the new device fall within the intended use of the predicate device.
- The manufacturer modifies the indications for use, explicitly or implicitly, by proposing a different surgical implantation method which also affects the indications for use, e.g., a minimally invasive procedure in place of an open procedure, and the safety and effectiveness of the new device cannot be adequately replicated or otherwise characterized in a non-clinical performance (including animal) test environment to adequately support substantial equivalence to the predicate. Although on its face a minimally invasive procedure would appear to involve less serious risks than an open procedure, the minimally invasive procedure may be less effective or may present different but still serious risks.

2. Technological Differences

FDA may request clinical data for a 510(k) when the technological differences between the new device and predicate device are significant but do not support an immediate NSE determination due to different questions of safety and effectiveness. In these limited situations, clinical data may be needed to evaluate the safety and effectiveness of the new device as compared to the predicate device.

Illustrative Examples:

- A new IVD uses the same analyte-specific chemistry as the predicate, but with a different read-out technology (e.g., chemiluminescence instead of colorimetry). Clinical data may be necessary to demonstrate that the new device performs equivalent to the predicate.
- Performance characteristics of the new device in comparison to the predicate are significantly different in non-clinical performance testing, e.g., the predicate is rigid whereas the new

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device is designed to be more flexible. Clinical data may be necessary to demonstrate that the new device performs equivalent to the predicate.

- Some devices that display data about the patient's anatomy or physiology, e.g., glucose meters, pulse oximeters, blood pressure cuffs, are supported by software. If there is a change in the software that relates to how the software analyzes the patient's anatomy or physiology, the device may need to be tested on actual patients to assure that the software performs in a manner that is equivalent to the previous version. In this case, non-clinical data may not suffice.
- The technological characteristics of the new device raise a question concerning whether its clinical performance can be expected to be equivalent to the clinical performance of the predicate. Clinical data may be necessary to demonstrate that the new device performs equivalent to the predicate. For IVDs, an example is a new prothrombin time (clotting) test using thromboplastin that is a recombinant product instead of a naturally occurring material.

3. *Non-clinical Testing Methods are Limited or Inappropriate Because of the Indications for Use or Device Technology*

FDA requests clinical data for a 510(k) submission to address issues that cannot be adequately addressed using non-clinical test methods because of the indications for use or device technology. For instance, for certain indications or technologies, FDA may request clinical data when non-clinical testing methods are not validated, are limited or are inappropriate, because of either their scope or their applicability, to demonstrate substantial equivalence.

Illustrative Examples:

- For some devices, the way they are used and the environment in which they are used affect the way they perform. For example, the non-clinical performance testing on the new device may be insufficient to support a substantial equivalence determination if the testing cannot replicate the way the device will be used or the way similar devices have been demonstrated to fail in a clinical setting. Although the non-clinical testing for these devices might be informative for many other aspects of the device, it may be necessary to supplement the non-clinical data with clinical simulation performance data or clinical performance data.
- If the non-clinical testing of a device raises safety concerns that cannot be mitigated or answered through non-clinical testing, such a device may require clinical testing to assure that the safety questions are not greater than those raised by the predicate device.

New scientific information may affect FDA's expectations concerning the type and level of performance data included in a 510(k) submission. For device types with long histories of safe use and well understood mechanisms of action, more limited performance testing data may be sufficient. On the other hand, a pattern of adverse events or published literature documenting poor clinical outcomes with a particular technology may lead FDA to reconsider its regulatory approach to premarket submissions for such technology.³⁷ Should FDA change its scientific decision making

³⁷ See [SOP: Decision Authority for Additional or Changed Data Needs for Premarket Submissions](http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm279288.htm) (<http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/ucm279288.htm>).

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with regard to a particular device, FDA will consider its options (e.g., guidance, advisory panel meeting, etc.), for explaining such change and the basis for the decision to ensure transparency in the change in policy. FDA also intends to consider any pending 510(k) submissions that may be affected by the change or allow for an appropriate transition period, in certain situations that may affect the industry at large.

G. The 510(k) Summary

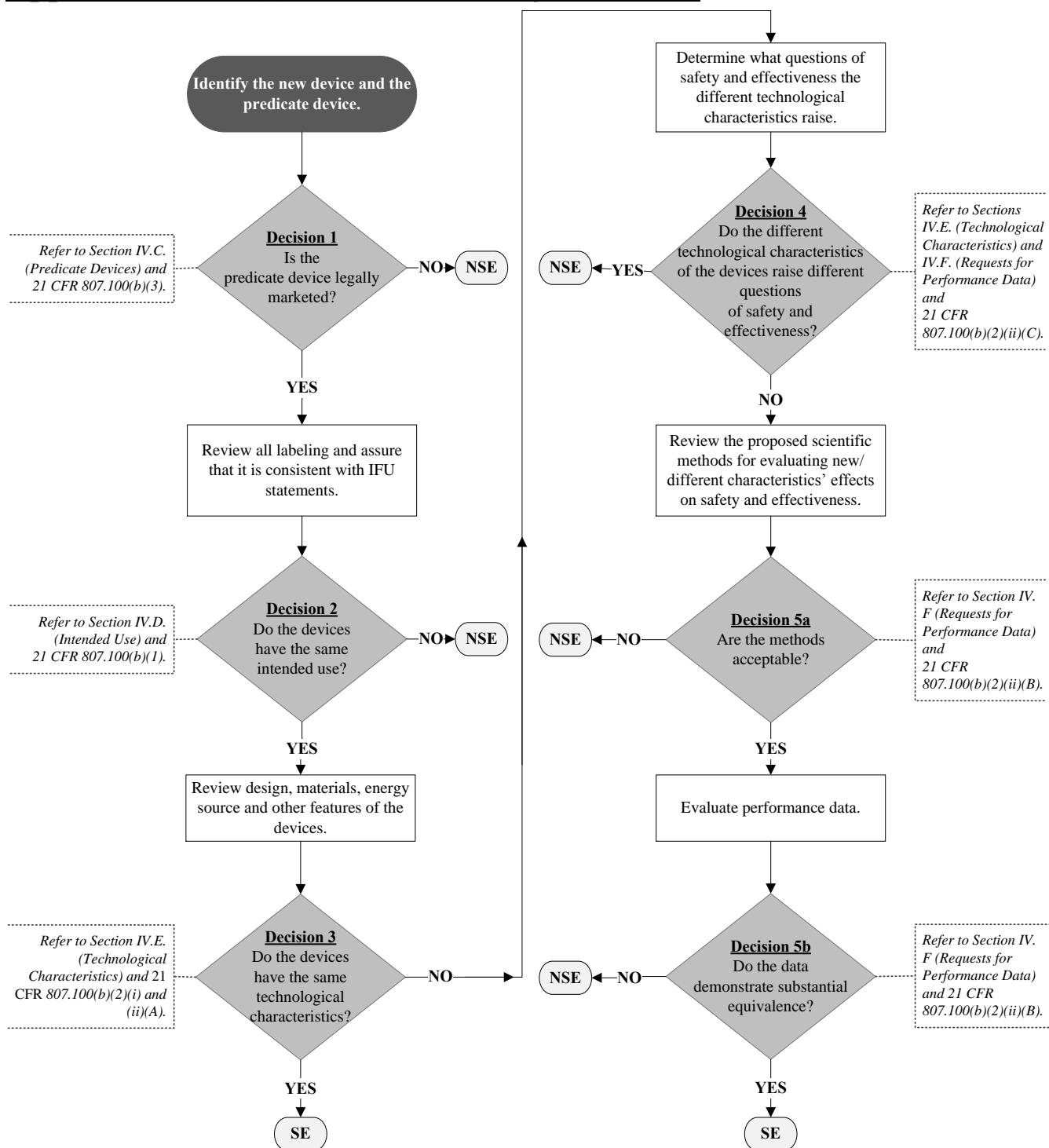
The 510(k) Summary³⁸ is a document that provides a high-level discussion of the content of a 510(k) and must include all the elements identified in 21 CFR 807.92. A 510(k) Summary must be in sufficient detail to provide an understanding of the basis for a determination of substantial equivalence (21 CFR 807.92(a)).

In an effort to improve the transparency and predictability of the 510(k) program and to ensure that the 510(k) Summary reflects the information provided in a 510(k) submission to support a substantial equivalence determination, FDA intends to verify the accuracy and completeness of the information included in a 510(k) Summary.

Although the 510(k) Summary is a document created by the manufacturer and is included in the 510(k), revisions to the 510(k) Summary may be necessary to accurately reflect the FDA's decision-making process. For example, manufacturers may have identified several devices as potential predicate devices, whereas, in the course of FDA's substantial equivalence evaluation, FDA may have determined that only one of these devices is an appropriate predicate device. In addition, it is possible during the course of FDA's review of the 510(k), that additional information or testing may be requested and submitted. Consequently, the manufacturer may be requested to update the 510(k) Summary to accurately include and convey the information identified in 21 CFR 807.92 and which was used to support the final decision-making process.

In **Appendix B**, FDA describes the requirements of the content to be included in a 510(k) Summary, in accordance with 21 CFR 807.92, and provides guidance on the information to be included in a 510(k) Summary to ensure compliance with 21 CFR 807.92 and consistency in the level of information conveyed and captured in the 510(k) Summaries which are available to the public on FDA's website. In **Appendix C**, FDA has provided a hypothetical 510(k) Summary in order to demonstrate the recommended level of detail for each section.

³⁸ As specified in 21 CFR 807.87(h), a 510(k) Statement as described in 21 CFR 807.93 may be provided in lieu of a 510(k) Summary. However, in order to facilitate transparency, FDA encourages all submitters to utilize the 510(k) Summary option.

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SE = "Substantially Equivalent"
 NSE = "Not Substantially Equivalent"
 IFU = "Indications For Use"

This Flowchart is not intended to be used as a 'stand-alone' document and should only be considered in conjunction with the accompanying text in this guidance.

*Contains Nonbinding Recommendations***Appendix B. The 510(k) Summary Document Requirements**

In Appendix B, FDA provides further clarification and guidance to facilitate compliance with the requirements set forth in 21 CFR 807.92 and consistency in the information conveyed in the 510(k) Summaries which are available to the public on FDA's website. As noted earlier in this guidance document, if during the course of review, additional testing or information are requested, the manufacturer should submit a revised 510(k) Summary to reflect the additional information. The following identifies the information that must be included in the 510(k) Summary under 21 CFR 807.92, information that we recommend be included in the 510(k) Summary, and other considerations.

- 807.92(a)(1): "The submitter's name, address, telephone number, a contact person, and the date the summary was prepared."
 - The "submitter" or manufacturer should be the holder of the 510(k), not a consultant or law firm.
- 807.92(a)(2): "The name of the device, including the trade or proprietary name if applicable, the common or usual name, and the classification name, if known."
 - FDA recommends that the manufacturer list all applicable names and model numbers, if known.
 - If the submission is bundled³⁹, the 510(k) Summary should list all applicable classification regulations and product codes.
- 807.92(a)(3): "An identification of the legally marketed device to which the submitter claims equivalence. A legally marketed device to which a new device may be compared for a determination regarding substantial equivalence is a device that was legally marketed prior to May 28, 1976, or a device which has been reclassified from class III to class II or I (the predicate), or a device which has been found to be substantially equivalent through the 510(k) premarket notification process."
 - FDA recommends that the manufacturer provide the 510(k) number of the device used as the predicate device in support of the current 510(k) submission.
 - If using an exempt device as a predicate, the manufacturer should list the classification regulation and the product code.
 - If using a device that has been reclassified from Class III to II as a predicate, where a 510(k) has not been submitted, please list the PMA number.
 - If the manufacturer lists an inappropriate predicate device, FDA will request that such information be removed and the 510(k) Summary updated accordingly by the manufacturer.
- 807.92(a)(4): "A description of the device that is the subject of the premarket notification submission, such as might be found in the labeling or promotional material for the device, including an explanation of how the device functions, the scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device, such as device design, material used, and physical properties."

³⁹ See Guidance for Industry and FDA Staff, "[Bundling Multiple Devices or Multiple Indications in a Single Submission](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089732.pdf)" (<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089732.pdf>).

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The description of the device attributes should include the following details:

- Device Identification:
 - List all key device components included in the submission (e.g., catheter, cable wire, leads)
 - List all model numbers (if known) and briefly explain the differences among models
- Device Characteristics (address all that apply):
 - software
 - biologics
 - drugs
 - any patient-contacting materials
 - coatings
 - additives
 - single-use
 - sterile
 - sterilization method [specify]
- Environment of Use (address all that apply):
 - healthcare facility/hospital
 - home
 - other [specify]
- Brief Written Description of the Device:
 - Explanation of how the device works/principle of operation
 - Mechanism of action
 - Any necessary feature to determine SE or device performance
 - Energy source (if applicable)
- Materials of Use
 - General type of material used (e.g., polysulfone, stainless steel)
 - If material conforms to an FDA recognized consensus standard for medical use, include the applicable number (e.g., ASTM FXXXX-last 2 numbers of the year)
 - Duration and type of contact
- Key Performance Specifications/Characteristics of the Device
- 807.92(a)(5): “A statement of the intended use of the device that is the subject of the premarket notification submission, including a general description of the diseases or conditions that the device will diagnose, treat, prevent, cure, or mitigate, including a description, where appropriate, of the patient population for which the device is intended. If the indication statements are different from those of the legally marketed device identified in paragraph (a)(3) of this section, the 510(k) summary shall contain an explanation as to why the differences are not critical to the intended therapeutic, diagnostic, prosthetic, or surgical use of the device, and why the differences do not affect the safety and effectiveness of the device when used as labeled.”

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- The 510(k) Summary should include the Indications for Use, which should be identical to that proposed on the Indications for Use Sheet and the labeling.
 - If the Indications for Use are different from those of the predicate device, a brief explanation is required to address why the differences in the Indications do not affect the safety and effectiveness of the device and do not alter the intended therapeutic, diagnostic, prosthetic, or surgical use of the device.
- 807.92(a)(6): “If the device has the same technological characteristics (i.e., design, material, chemical composition, energy source) as the predicate device identified in paragraph (a)(3) of this section, a summary of the technological characteristics of the new device in comparison to those of the predicate device. If the device has different technological characteristics from the predicate device, a summary of how the technological characteristics of the device compare to a legally marketed device identified in paragraph (a)(3) of this section.”
 - 807.92(b): “510(k) summaries for those premarket submissions in which a determination of substantial equivalence is also based on an assessment of performance data shall contain the following information:”
 - “(1) A brief discussion of the nonclinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence,”
 - A high level summary of the tests that were used to demonstrate substantial equivalence should be included (e.g., fatigue testing, biocompatibility, etc.).
 - If a guidance document was referenced/used for the testing, the guidance document should be referenced in this section.
 - If an FDA recognized consensus standard (e.g., test method or guide) was used/relied upon for testing, please list the standard connotation (e.g., ASTM FXXXX-last 2 numbers of the year).
 - “(2) A brief discussion of the clinical tests submitted, referenced, or relied on in the premarket notification submission for a determination of substantial equivalence. This discussion shall include, where applicable, a description of the subjects upon whom the device was tested, a discussion of the safety or effectiveness data obtained from the testing, with specific reference to adverse effects and complications, and any other information from the clinical testing relevant to a determination of substantial equivalence,”
 - FDA is interested in collecting an appropriate degree of detail within this section to be informative regarding the level of evidence that was necessary to support an SE determination.
 - As applicable, FDA recommends the following details be included regarding the clinical evidence provided to support an SE determination:
 - Level of Evidence (identify one)
 - Randomized, multi-arm, “blinded” study with concurrent sham (placebo) control
 - Randomized, multi-arm, “blinded” study with concurrent (“active”) control
 - Randomized, multi-arm, un“blinded” study with a control (control that is either active or consists of no treatment)
 - Non-randomized study with concurrent (“active”) control
 - Single-arm study with patient serving as own control (include designed single-arm crossover)
 - Single-arm study with Historical Control (using patient-level data)

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- Single-arm study with Literature Control (historical control)
 - Single-arm study with Objective Performance Criteria
 - Single-arm study with Performance Goals
 - Registry
 - Observational study
 - Systematic review (meta-analysis with patient-level data)
 - Meta-analysis based on summary information only
 - Literature Summary
 - Uncertain
- Location of Study (specify one of the following)
 - United States only
 - outside of United States only
 - both in United States and outside of United States
 - Identify applicable IDE number [Gxxxxxx]
 - Primary Safety Endpoint Identified?
 - If Yes, describe
 - Primary Effectiveness Endpoint Identified?
 - If Yes, describe
 - Primary Composite Safety/Effectiveness Endpoint Identified, if applicable?
 - If Yes, describe
 - Patient Accountability (Enter number of patients reported at each stage):

| Stage | Investigational Device Arm Total | Control Arm Total | Total |
|--|-------------------------------------|----------------------|-------|
| Enrollment | | | |
| Treatment | | | |
| Primary Safety Endpoint Analysis | | | |
| Primary Effectiveness Endpoint Analysis | | | |
| Primary Composite Safety/Effectiveness (if app) | | | |

The content of the table may need to be modified depending upon the specifics of the clinical data provided and the endpoints studied.

- Identify whether the study met the primary endpoint
 - Whether Yes or No, describe
- Describe the study results in appropriate parameters
- Identify the adverse events and complications observed in the study, including those associated with the device.

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“(3) The conclusions drawn from the nonclinical and clinical tests that demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed device identified in paragraph (a)(3) of this section.”

- A brief summary of why the device is substantially equivalent to the predicate.
- 807.92(c): “The summary should be in a separate section of the submission, beginning on a new page and ending on a page not shared with any other section of the premarket notification submission, and should be clearly identified as a ‘510(k) summary’.”
- 807.92(d): “Any other information reasonably deemed necessary by the agency.”
 - If the FDA determines that other information needs to be included within the 510(k) Summary, such information must be included within this document.

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Appendix C. Sample of 510(k) Summary Complying with 21 CFR 807.92

510(k) Summary

I. SUBMITTER

Device Submitter, Inc.
123 Main Street
Anywhere, MD 01234

Phone: 555-555-1234
Fax: 555-555-0123

Contact Person: John Contact
Date Prepared: May 16, 2013

II. DEVICE

Name of Device: Brand X Endoscopic Stapling System, Model x123, Model y456
Common or Usual Name: Endoscopic Stapling System
Classification Name: Endoscope and Accessories (21 CFR 876.1500)
Regulatory Class: II
Product Code: ODE

III. PREDICATE DEVICE

Brand Z Endoscopic Plication System, KXXXXXXX
This predicate has not been subject to a design-related recall.⁴⁰

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

The Brand X Endoscopic Stapling System consists of a flexible endoscope, an endoscopy suite, and a number of associated accessories. The endoscope and staples are provided sterile (EtO).

Brand X uses an implant (surgical staple) that is delivered by a flexible endoscope by a surgeon or gastroenterologist for approximating adjoining portions of the esophageal and gastric tissues at the gastroesophageal junction, thereby creating a permanent surgical fundoplication. The system includes an ultrasonic transducer that operates as a range finder for measuring the relative alignment and the distance between the transducer at the tip of the endoscope (the anvil) and the ultrasonic mirror in the

⁴⁰ On July 9, 2012, section 605 of FDASIA (Pub. L. 112-144) added section 518A to the FD&C Act, which directs FDA to establish a program to routinely and systematically assess information regarding device recalls, and to use that information to proactively identify strategies for mitigating health risks presented by defective or unsafe devices. FDA believes that one way to carry out this directive is to provide greater transparency on recalled devices. Identifying whether a predicate was recalled is optional, but doing so would help the Agency achieve this FDASIA directive.

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cartridge (that includes the staples). The device deploys sets of implantable staples for performing the fundoplication procedure.

The system combines a video camera, an ultrasonic range finder and a surgical stapler in a single unit. The flexible endoscope includes light guides, irrigation, air insufflation and suction channels that terminate at the endoscope tip. The stapler portion includes a cartridge that contains sterile 4.8 mm standard "B" shaped titanium surgical staples. Model x123 includes five (5) staples per cartridge, while Model y456 contains only four (4). The tip of the endoscope contains an anvil for the staples, as well as two small stainless steel screws that are extracted from the tip of the endoscope and engage into nuts positioned in the cartridge. The ultrasonic range finder measures the distance between an ultrasonic mirror in the cartridge and the tip of the endoscope. It also verifies alignment between the cartridge and the anvil, before insertion of the screws.

The endoscopy suite includes the ISL (Insufflation, Suction and Light) console, the CCU (Camera Control Unit) console and a monitor. The ISL console provides suction, insufflation and a white light (Xenon) source for illumination. The CCU console contains a controller for the camera, ultrasonic range finder and sensors that indicate status of the bending angle, screws and fire. The monitor displays patient information, the video image, and the processed data from the controllers such as ultrasonic data, fire status, degree of bending and screw position. A keyboard for entering data during the procedure is also included. The System includes three software applications: the video controller software, the ultrasound controller software, and the ISL controller software. The software systems work in conjunction with the hardware consoles listed above in order to visualize the procedure and deliver the staples. The endoscope is designed for single-patient use, and it is connected to the CCU and ISL consoles via a multi-connector. The endoscope handle contains the controls used by the operator to manipulate the endoscope.

The associated accessories include:

- Irrigation bottle with liquids for irrigation of the camera lens
- Suction canister for extracting liquids during the procedure
- Silicon tubes for connecting the ISL and other accessories to the endoscope
- Disposable air filter of the suction ISL input channel
- Overtube for protecting patient's pharynx

V. INDICATIONS FOR USE

The Brand X Stapling System is indicated for the endoscopic placement of surgical staples in the soft tissue of the esophagus and stomach in order to create anterior partial fundoplication for treatment of symptomatic chronic Gastro Esophageal Reflux Disease (GERD) in patients who require and respond to pharmacological therapy.

The Indications for Use statement for the Brand X device is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for the treatment of GERD, by approximating tissue in the esophagus and stomach.

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VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Transoral endoscopic fundoplication is the technological principle for both the subject and predicate devices. It is based on the use of endoscopic instrumentation for approximating and permanently adjoining gastric and esophageal tissues, creating plications at the level of the gastroesophageal valve and thereby restoring valvular functionality and reducing gastric reflux into the esophagus.

At a high level, the subject and predicate devices are based on the following same technological elements:

- Endoscope – used to reach the target tissue
- Device inserted through an overtube – to protect the esophagus
- Creation of a gastric (or gastroesophageal) plication in close proximity to the gastroesophageal junction by the retroflexed device
- Use of a permanent implant to secure tissue
- Use of a mechanical component for positioning and launching the implant
- User-controlled mechanical trigger (or knob) to launch the fastener (implant)
- Mechanically securing the plication by a permanent implant fastener

The following technological differences exist between the subject and predicate devices:

- Use of an ultrasound range finder
- Use of a staple as a fastener
- Use of different tissue capture and fixation mechanisms
- The predicate device must be used in conjunction with a flexible endoscope whereas the subject device has a flexible endoscope incorporated into the system.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the Brand X device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 “Use of International Standard ISO-10993, ‘Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,’” May 1, 1995, and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation
- Systemic toxicity
- Pyrogen Testing

The endoscopic delivery system is considered tissue contacting for a duration of less than 24 hours, while the staples are considered permanent implants. The titanium staple material conforms to ASTM F-67-06 for chemical composition.

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Electrical safety and EMC testing were conducted on the Brand X device, consisting of the ISL console, CCU console and endoscope. The system complies with the IEC 60601-1, IEC 60601-2-18 and IEC 60601-2-37 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Mechanical and acoustic testing

- Acoustic Testing
- Elongation of the bending cable
- Torque on the handle wheel and force on cable
- Crimp assembly, cable tensile strength, cable flexibility, minimum bending radius of the cables
- Staple verification
- Simulated use testing

Animal Study

In the animal study conducted, 16 pigs underwent endoscopy with the Brand X System. Twelve pigs underwent fundoplication, and 4 pigs served as a sham (control) group. There were no procedure related complications or premature deaths in this study, at the 2, 4 and 6 week follow-up (4 pigs in each group).

The safety and feasibility of the Brand X device were evaluated by macroscopic and histological evaluation of the tissue in the treatment stapled areas. These studies demonstrated that the Brand X device can safely create an anterior partial fundoplication, similar to that which is constructed using other endoscopic suturing devices.

Clinical Studies

Clinical testing of the Brand X device included an initial feasibility study of 6 patients, a pilot study consisting of 13 patients and a pivotal study of 72 patients. Substantial equivalence was based in part on the pivotal study.

Pivotal Study

The pivotal study was a prospective, multi-center, open label, non-randomized, single arm study of 72 patients, of which 66 were available for primary endpoint analysis; 3 subjects did not complete the procedure, and 3 were excluded from the effectiveness analysis. The device was used to staple the fundus of the stomach to the esophagus, using standard B shaped surgical staples. Stapling was performed in two or three locations at least 1.5 cm above the GE junction, separated by at least 90 degrees. The procedure was intended to create a partial anterior fundoplication as a reflux barrier. Patients were followed for a period of six months at 6 sites both in the United States and outside of the United States under IDE G070136.

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Primary effectiveness endpoint:

GERD health related quality of life score (GERD-HRQL) off proton pump inhibitor (PPI) was improved from baseline by > 50%, at six months post procedure in at least 53% of the patients (53% is the lower boundary of the 95% confidence interval).

Primary safety endpoint:

The primary safety endpoint consisted of all treatment-related adverse events, during and after the procedure. "Treatment-related" events were conventionally defined as those which occurred in the first 30 days post-procedure.

Effectiveness

The primary endpoint for the Brand X study focused on the GERD-HRQL score. The study results demonstrated that 75% of the patients had a >50% improvement in their GERD-HRQL score off PPI at six months compared to baseline. Hence the study met its primary endpoint with the required 95% confidence level.

The reduction in the median score for the Brand X device of 23.0 units (from 29.0 to 6.0) represents a 79.3% improvement. This value is almost identical to the published result for the pivotal trial of the predicate device (79.2%). Therefore, the effectiveness of the Brand X system in successfully treating chronic symptoms of GERD is similar to the effectiveness reported for the predicate device.

The median value of the percent of time pH < 4.0 decreased from an initial value of 8.3% at baseline to 6.75%. Therefore, the study met its secondary endpoint related to the acid exposure test. A comparison to results reported in the literature revealed that the change in the median values of the Brand X device showed a decrease of 19%, while the predicate showed a decrease of 18%. Hence, the Brand X results in reducing the exposure to gastric acids are similar to those reported for the predicate system.

Safety

The study reported nine patients with a total of nine serious adverse events (SAEs). Four events were considered mild in intensity, involving pain and fever. Three events were classified as moderate in intensity, involving pneumothorax, pneumomediastinum, and pneumoperitoneum (all resolved spontaneously). Two events were considered severe in intensity: one involved esophageal perforation (required drainage) and another had suicidal thoughts (non-device/procedure related).

Six of the SAEs were considered related to the device: one definitely (esophageal perforation) and the others possibly. Three events were considered not related to the device. The median time from procedure to SAE was 1.5 days for events related to the device. None of the patients with SAEs required any operation or re-operation. Adverse events reported that occurred in greater than the 5% level were postoperative pain or discomfort in 33% of patients, postoperative nausea in approximately 10%, and sore throat in 21%. The adverse events were mild or insignificant in most cases.

The SAEs and overall safety profile were similar to the predicate device for which two perforations and one bleeding event were reported. The number of AEs was similar to those reported for the predicate device. Three cases of fever were reported in the current study (for 72 patients), similar to the 3 cases of fever reported for the predicate. There were 23 cases of chest pain (23/72 = 32%) vs. 17% reported for the predicate; abdominal pain was recorded for 5% of the patients in the current

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study vs. 44% of the patients for the predicate. Sore throat was reported for 15 patients ($15/72 = 21\%$) vs. 15% for the predicate.

Summary

Based on the clinical performance as documented in the pivotal clinical study, the Brand X system was found to have a safety and effectiveness profile that is similar to the predicate device.

VIII. CONCLUSIONS

Since the predicate device was cleared based in part on the results of clinical studies, and since the comparison of bench testing to clinical outcomes is still not well understood for this type of device, clinical testing was required to support substantial equivalence. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the Brand X device should perform as intended in the specified use conditions. The clinical data demonstrate that the Brand X device performs comparably to the predicate device that is currently marketed for the same intended use.

*Contains Nonbinding Recommendations***Appendix D. Glossary of Significant Terminology**

The following terms are defined for purposes of this guidance:

Classification regulation – The classification regulations are Agency-defined categories of medical devices based on intended use and technology. Each device classification regulation defines the class (i.e., Class I, II, or III) for the device category which in turn determines the regulatory requirements. Device classification regulations are codified by rule or order in 21 CFR Parts 862-892.

Indications for use – The disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

Intended use – The general purpose of the device or its function. The intended use of a device encompasses the indications for use.

Multiple Predicate Devices – Two or more predicate devices that have been provided to support an SE determination. If using multiple predicate devices to demonstrate substantial equivalence, each predicate device must have the same intended use as the new device, and any different technological characteristics between the new device and the predicate devices must not raise different questions of safety and effectiveness.

Performance Data – Performance data can be any data, including non-clinical (e.g., data from engineering testing, such as fatigue, wear, corrosion, etc., biocompatibility, functional animal studies, cadaver, etc.) and/or clinical, that are provided to support the substantial equivalence of a device that is intended to be marketed.

Predicate Device – A legally marketed device (as defined in 21 CFR 807.92(a)(3)) to which a new device may be compared for a determination regarding substantial equivalence because the devices have the same intended use and the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness.

Primary Predicate Device – A predicate device with indications for use and technological characteristics that are most similar to the new device. The primary predicate should be identified within a 510(k) submission.

Reference Device – A legally marketed device that is intended to provide scientific and/or technical information (e.g., test methodology) to help address the safety and effectiveness of a new technological characteristic. Reference devices are not predicate devices and may only be used after Decision Point 4 on the 510(k) Decision-Making Flowchart.

Split Predicate – Using one legally marketed device for intended use and a different legally marketed device for technological characteristics to demonstrate substantial equivalence. The use of a “split predicate” is inconsistent with the 510(k) regulatory standard.

EXHIBIT DX10

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

US District Court Electronic Case Filing System
District of Utah (Central)
CIVIL DOCKET FOR CASE #: 2:10-cv-01283-RJS

Braun et al v. Medtronic Sofamor Danek et al
Assigned to: Judge Robert J. Shelby
Case in other court: Tenth, 15-04173
Cause: 28:1332 Diversity-Breach of Contract

Date Filed: 12/30/2010
Date Terminated: 07/08/2014
Jury Demand: Plaintiff
Nature of Suit: 190 Contract: Other
Jurisdiction: Diversity

| Date Filed | # | Docket Text |
|------------|-----|---|
| 02/05/2014 | 535 | Minute Order. Proceedings held before Judge Robert J. Shelby: The court hears oral argument on a number of motions. For the reasons stated on the record, the court rules on the following motions: Plas MOTION in Limine and Memorandum in Support Daubert Motion in Limine #4 to Preclude MSD Testimony re Sound and Reasonable Judgment, docket entry 408 is granted in part. The court will not grant a sweeping motion to exclude all fact and expert testimony relating to sound and reasonable judgment. The court finds that the expert testimony, to the extent addressed in this motion, was based upon sufficient facts and data to satisfy Rule 702. The court does not view Medtronics defense as the traditional advice of counsel defense that justifies broad exclusion of documents. Out of concerns about privilege, the court will exclude evidence that Medtronic relied on legal advice of its cnsl when determining whether to prosecute Dr. Brauns patent. The court will consider an appropriate jury instruction on patent attorney consultation at trial. For similar reasons, Plas MOTION in Limine and Memorandum in Support Daubert Motion in Limine #5 to Exclude Speculation re Bevan and Breard Patents, docket entry 409 is denied. The court is not persuaded that broad exclusion is appropriate under Rule 702, where the experts relied on sufficient facts and data. To the extent that the testimony speculates on decisions of the USPTO, Dr. Braun may raise timely objections at trial. For similar reasons, Plas MOTION in Limine and Memorandum in Support Daubert Motion in Limine #6 to Exclude Evidence that MSD's Existing Intellectual Property Included Dr. Braun's Concepts, docket entry 410 is also denied for the reasons stated in the briefing and because the expert opinions are based on sufficient facts and data. The court also concludes that the issue of active correction is the proper subject of cross-examination at trial. To the extent the motion raises the possibility of exclusion of late produced documents, the court has already addressed the issue. The court does not rule on Plas MOTION in Limine and Memorandum in Support Daubert Motion in Limine #7 to Exclude William Richter, docket entry 411 , which is subject to additional briefing. Plas MOTION in Limine and Memorandum in Support Daubert Motion #8 to Exclude Rodney Ballard, docket entry 412 is denied without prejudice. The court concludes that Mr. Ballards testimony will be limited to the subjects listed in the disclosure, and that Dr. Braun should be permitted to raise timely objections to foundation during the trial. Dft's MOTION in Limine and Memorandum in Support Daubert Motion to Exclude Subjects of Michael Collins's Testimony, docket entry 421 is granted. Mr. Collins may not vouch for certain facts or evidence, and the court will consider an admonishment if Mr. Collins opines on the veracity of facts. Plas MOTION in Limine and Memorandum in Support Daubert Motion in Limine #9 to Exclude Karen Becker and Timothy Ulatowski, docket entry 413 is granted in part. The court concludes that Ms. Becker may not provide an opinion on legal interpretation of the contractual provisions, and neither FDA expert may |

speculate on what the FDA would have done. Neither witness will be permitted to instruct the jury on the law. The court, however, will consider objections on the issues of duplicate testimony and foundation at trial. Dfts Defendant's MOTION in Limine and Memorandum in Support Gaubert [sic] Motion regarding John Guynn's Methodology, docket entry [427](#) and Dfts SEALED Daubert MOTION Regarding the Qualifications of Plaintiff's Expert John Guynn, docket entry [430](#) are granted in part, subject to the same limitations as the Plas motions to exclude patent expert testimony. For example, Mr. Guynn may testify at trial; however, he may not instruct the jury on legal standards or testify on subjects for which he is not skilled in the art. Dfts Defendant Medtronics Daubert Motion to Exclude Subjects of Michael Collinss Testimony, docket entry [422](#) is granted in part. Mr. Collins is not an expert in the art of fusionless technology and may not opine on the scope of the patents or the intent or purpose of Medtronic. Mr. Collins may provide an expert opinion on the royalty agreements and possibly FDA regulatory practice, subject to cross-examination. The parties stipulated that Mr. Collins may rely on the five percent royalty rate in the License Agreement License. The court sets the following schedule: Additional motion hearing and final pretrial conference set for 2/7/2014 at 10:00 a.m. Further trial related matters will be heard on 2/14/2014 at 10:00 a.m. Written Order to follow oral order: No. Attorney for Plaintiff: Alan Bradshaw, Chad Derum, Roger Dodd, Brent Manning; Attorney for Defendant John Adams, Ryan Bell, Greg Newman, James Jardine, Jennifer Leigh Truelove. Court Reporter: Ray Fenlon. (mjm) (Entered: 02/11/2014)

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EXHIBIT DX11

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

C E R T I F I C A T E

I, TIMOTHY A. ULATOWSKI, hereby certify that I have carefully read the foregoing transcript, and that the same is a true and complete, full and correct transcription of my deposition, except:


| PAGE/LINE | CHANGE | REASON |
|-------------------|--|----------------|
| P.9, l.20, | Add at end of line: “, in regard to the FAW devices cleared by the Cardiovascular Division.” | Clarification. |
| P. 88, ll. 1-2, | Replace “we don’t have” to “I don’t recall that we have”. | Clarification. |
| P. 96, l. 4: | Replace “No” with “I was provided those materials in an earlier litigation for the Bair Hugger, but did not recall having seen them at the time of my deposition.” | Accuracy. |
| p. 105, l. 19, | Add at the end of the sentence: “, and in the 69 hours recorded for the next month.” | Accuracy. |
| p. 116, l. 4, | Replace “It is what it is” with “The time I spent reviewing materials and writing a report for this MDL included the 44 hours plus the 69 hours I spent in the month of May.” | Accuracy. |
| p. 118, l. 23 | Change “us” to “me”. | Clarification. |
| p. 134, ll. 18-22 | Replace with: “As I said, the letter cited in my report referenced articles submitted to FDA. Reference to a clinical study also was submitted to Mr. Bird on August 8, 1990. 3MBH00047485 and 47488.” | Accuracy. |
| p. 182, l. 9 | Change “report” to “reports”. | Accuracy. |

p. 193, l. 2 Change "visible" to "transparent".

Clarification.

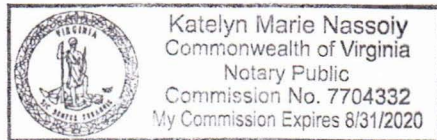
p. 258, l. 15 Delete "but".

Transcription
error.



TIMOTHY A. ULATOWSKI
Deponent

Signed and sworn to before me this 11th day of August, 2017.



Notary Public

EXHIBIT DX12

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

S118

TITLE: COMPARISON OF INTRAOPERATIVE WARMING DEVICES

Authors: JM Hynson M.D., DI Sessler M.D.

Affiliation: Department of Anesthesia, UCSF, San Francisco, CA 94143

Mild hypothermia remains an almost inevitable consequence of anesthesia and surgery. We therefore evaluated the efficacy of three intraoperative warming techniques.

With IRB approval, 12 patients undergoing kidney transplantation were randomly assigned to: 1) a full length (54 X 145 cm) circulating water blanket set at 40°C positioned under the subject (N=4); 2) humidification and heating to 40°C of inspired gases (N=3); 3) skin surface warming of the lower extremities (to mid thigh level), using a Bair Hugger® convective air warmer set on "high" (=43°C) (N=4); and 4) no extra warming (control) (N=5). Intravenous fluids were warmed in all groups. Fresh gas flows were maintained at 5 L/min without a heat and moisture exchanger. Ambient temperature and preoperative conditions were similar in all groups. Tympanic membrane temperature was measured starting 30 min before induction of anesthesia.

In all groups, tympanic membrane temperature decreased =0.7°C, during the first 30 min (fig.). Tympanic membrane temperatures in patients given forced air warming began to increase =60 min after induction. Those

given external warming with the circulating water blanket, had little further decrease in temperature after the first h of anesthesia. Central temperatures continued to decrease throughout the 3 h study period in the control and heated humidifier groups.

We conclude that convective air warming of the legs is more effective than the use of a circulating water blanket. Heated humidification offers little protection from intraoperative hypothermia.

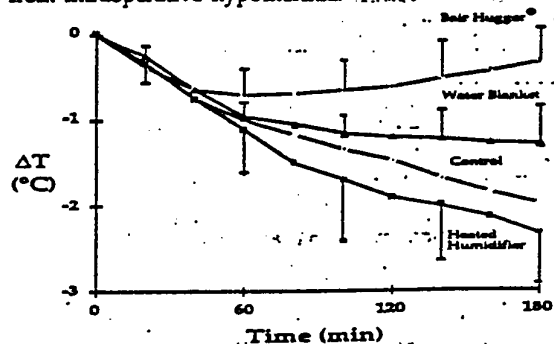


Figure. After initially decreasing, central temperature began to increase in patients given convective air warming. Error bars in the control group were deleted for clarity, but were similar to those in the other groups.

Supported by National Institutes of Health grant #R29 GM39723.

EXHIBIT DX13

**TO DECLARATION OF BRIDGET M. AHMANN
IN SUPPORT OF DEFENDANTS' MEMORANDUM IN
OPPOSITION TO PLAINTIFFS' MOTION TO EXCLUDE
OPINIONS AND TESTIMONY OF TIMOTHY ULATOWSKI**

Information about the Use of Forced Air Thermal Regulating Systems - Letter to Health Care Providers

August 30, 2017

Dear Health Care Provider,

The FDA is reminding health care providers that using thermoregulation devices during surgery, including forced air thermoregulating systems, have been demonstrated to result in less bleeding, faster recovery times, and decreased risk of infection for patients.

The FDA recently became aware that some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery). After a thorough review of available data, the FDA has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection.

Therefore, the FDA continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems) for surgical procedures when clinically warranted. Surgical procedures performed without the use of a thermoregulation system may cause adverse health consequences for patients during the postoperative and recovery process.

Forced air thermal regulating systems, also called forced air warmers or forced air warming systems, are devices used to regulate a patient's temperature during surgical procedures. Forced air thermal regulating systems use an electrical blower to circulate filtered, temperature controlled air through a hose into a blanket placed over or under a patient.

To determine if there is an increased risk of surgical site infection when forced air thermal regulating systems are used during surgery, the FDA collected and analyzed data available to date from several sources, including medical device reports received by the agency, information from manufacturers and hospitals, publically available medical literature, operating room guidelines, and ventilation requirements

As always, please follow the manufacturer's instructions for use in the operating room/and or the post-operative environment.

FDA ACTIONS

The FDA will continue to actively monitor this situation and will update this communication if significant new information becomes available.

CONTACT US

If you have questions about this communication, please contact CDRH's Division of Industry Communication and Education (DICE) at **DICE@FDA.HHS.GOV (mailto:DICE@FDA.HHS.GOV)**, 800-638-2041, or 301-796-7100.

Sincerely,

/s/

William Maisel, MD, MPH
Deputy Center Director for Science
Center for Devices and Radiological Health
U.S. Food and Drug Administration

More in **Letters to Health Care Providers**
(/MedicalDevices/Safety/LetterstoHealthCareProviders/default.htm)